

PALATIN TECHNOLOGIES INC  
Form S-1  
September 29, 2014

As filed with the Securities and Exchange Commission on September 29, 2014

**Registration No.**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**Form S-1**

**REGISTRATION STATEMENT  
*UNDER*  
***THE SECURITIES ACT OF 1933*****

**Palatin Technologies, Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

2834  
(Primary Standard Industrial  
Classification Code Number)

95-4078884  
(I.R.S. Employer  
Identification Number)

**4B Cedar Brook Drive  
Cranbury, New Jersey 08512  
(609) 495-2200**

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

**Stephen T. Wills**  
**Chief Financial Officer**  
**Palatin Technologies, Inc.**  
**4B Cedar Brook Drive**  
**Cranbury, New Jersey 08512**  
**(609) 495-2200**

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

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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 of 1933, 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

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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.

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

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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## CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price <sup>(1)(2)</sup>	Amount of Registration Fee
Common Stock, \$0.01 par value per share	\$ 57,500,000	\$ 7,406.00

Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act (1) of 1933, as amended. Includes the offering price of shares that the underwriters have the option to purchase to cover over-allotments, if any.

(2) Pursuant to Rule 416, this registration statement shall be deemed to cover additional securities that may be offered or issued to prevent dilution resulting from stock splits, stock dividends or similar transactions.

**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, as amended, 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 declared effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

**Subject To Completion, Dated September 29, 2014**

**Shares**

**PALATIN TECHNOLOGIES, INC.**

**Common Stock**

**\$ per share**

Palatin Technologies, Inc. is offering      shares.

Trading symbol: NYSE MKT    PTN

The last reported sale price for our common stock on September 26, 2014 was \$0.87.

**This investment involves risks. See Risk Factors beginning on page 5.**

	Per Share	Total
Public offering price	\$	\$
Underwriting discount and commissions	\$	\$
Proceeds, before expenses, to us	\$	\$

*The underwriters have a 30-day option to purchase up to      additional shares of common stock from us to cover over-allotments, if any.*

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

**Piper Jaffray**

The date of this prospectus is      , 2014.



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You should rely only on the information contained in this prospectus and any free writing prospectus prepared by us or on our behalf. We have not, and the underwriters have not, authorized anyone to provide you with different or additional information. If anyone provides you with different or additional information, you should not rely on it. The information in this prospectus is accurate only as of the date on the front of this prospectus. Our business, financial condition, results of operations and prospects may have changed since the date of this prospectus. This prospectus is not an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. You should not consider this prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

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## PROSPECTUS SUMMARY

*This summary highlights certain information appearing elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider prior to investing in our common stock. After you read this summary, you should read and consider carefully the more detailed information and financial statements and related notes that we include in this prospectus, especially the sections entitled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operation. If you invest in our securities, you are assuming a high degree of risk.*

*Unless we have indicated otherwise or the context otherwise requires, references in the prospectus to Palatin, the Company, we, us and our or similar terms refer to the operations of Palatin Technologies, Inc. and its subsidiary.*

### Overview

We are a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. Our programs are based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. Our primary product in clinical development is a combination drug-device product for the delivery of bremelanotide for the treatment of female sexual dysfunction, or FSD. In addition, we have drug candidates or development programs for obesity, erectile dysfunction, cardiovascular diseases, pulmonary diseases, inflammatory diseases and dermatologic diseases.

The following drug development programs are actively under development:

Bremelanotide, an on-demand subcutaneous injectable peptide melanocortin receptor agonist, for treatment of FSD in premenopausal women. Bremelanotide, which is a melanocortin agonist (a compound which binds to a cell receptor and activates a response), is a synthetic peptide analog of the naturally occurring hormone alpha-MSH (melanocyte-stimulating hormone). The novel mechanism of action involves activating endogenous melanocortin hormone pathways involved in sexual arousal response. Bremelanotide is scheduled to start Phase 3 clinical trials in the last quarter of calendar 2014;

Melanocortin receptor-4, or MC4r, compounds for treatment of obesity and diabetes in collaboration with AstraZeneca pursuant to our research collaboration and license agreement. Results of our studies involving MC4r peptides suggest that certain of these peptides may have significant commercial potential for treatment of conditions responsive to MC4r activation, including FSD, erectile dysfunction, obesity and diabetes;

PL-3994, a peptide mimetic natriuretic peptide receptor A, or NPR-A, agonist, for treatment of cardiovascular and pulmonary indications. PL-3994 is our lead natriuretic peptide receptor product candidate, and is a synthetic mimetic of the neuropeptide hormone ANP. PL-3994 is in development for treatment of heart failure, acute exacerbations of asthma and refractory hypertension; and

Melanocortin receptor-1, or MC1r, agonist peptides, for treatment of inflammatory and dermatologic disease indications. Our MC1r peptide drug candidates are highly specific, with substantially greater binding and efficacy at MC1r than at other melanocortin receptors. We have selected one of our MC1r peptide drug candidates, designated PL-8177, as a clinical trial candidate.

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The following chart shows the status of our drug development programs:

## **Our Strategy**

Key elements of our business strategy include:

Using our technology and expertise to develop and commercialize products in our active drug development programs;  
Entering into strategic alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of product candidates that we are developing;  
Partially funding our product development programs with the cash flow generated from research collaboration and license agreements and any potential future agreements with third parties; and  
Completing development and seeking regulatory approval of bremelanotide for FSD and our other product candidates.

## **Risks Related to Our Business**

Our business is subject to numerous risks and uncertainties, including those highlighted in the section of this prospectus entitled **Risk Factors** immediately following this prospectus summary, which you should read carefully before deciding to invest in our common stock. These risks include, among others, the following:

We have incurred substantial losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future. We expect to incur additional losses as we continue our development of bremelanotide for FSD, PL-3994 and other product candidates and, unless and until we receive regulatory approval under applicable regulatory requirements, we cannot sell our products and will not have product revenues from them;  
We are substantially dependent on the clinical and commercial success of our product candidates, primarily our lead product candidate, bremelanotide for FSD, for which we are preparing to initiate Phase 3 clinical trials;  
We may be unable to obtain regulatory approval for bremelanotide for FSD or future product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations;  
Even if bremelanotide for FSD or our other product candidates receive regulatory approval, they may fail to achieve the level of market acceptance needed for us to have commercial success;  
Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration and expansion;

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We will require substantial additional funding to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts;

We have limited control over development activities in Europe for our lead product candidate, bremelanotide for FSD, including regulatory approvals, and no direct control over commercialization efforts due to an agreement with Gedeon Richter Plc, or Gedeon Richter. If Gedeon Richter fails in obtaining regulatory approval or market acceptance of bremelanotide for FSD in Europe, we may be unable to generate any revenue or business for bremelanotide for FSD in Europe;

If our efforts to protect our intellectual property related to bremelanotide for FSD or any future product candidates are not adequate, we may not be able to compete effectively in our market; and

We rely on a small management team and staff as well as various contractors and consultants to provide critical services to us, including services related to our clinical programs for bremelanotide and PL-3994 and our preclinical programs for MC1r and MC4r peptide drug candidates. Such programs could be adversely affected if we lose the services of existing key personnel.

## **Corporate Information**

We were incorporated under the laws of the State of Delaware on November 21, 1986 and commenced operations in the biopharmaceutical area in 1996. Our corporate offices are located at 4B Cedar Brook Drive, Cranbury, New Jersey 08512 and our telephone number is (609) 495-2200. Our internet address is *www.palatin.com*. The information on our website is not incorporated by reference into this prospectus and should not be considered to be part of this prospectus. Our website address is included in this prospectus as an inactive textual reference only.

Palatin Technologies, Inc. and the Palatin logo are our trademarks. All other trademarks and service marks appearing in this prospectus are the property of their respective owners.

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## THE OFFERING

Common stock offered by us

shares

Common stock to be outstanding after this offering

shares

Use of proceeds

We intend to use the proceeds from this offering to advance our Phase 3 clinical trials for bremelanotide for FSD, the clinical and preclinical development of our other product candidates and programs and working capital and general corporate purposes. See Use of Proceeds on page 32 for a more complete description of the intended use of the net proceeds from this offering.

Risk factors

You should read the section of this prospectus entitled Risk Factors beginning on page 5 and the other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in shares of our common stock.

NYSE MKT symbol

PTN

The number of shares of our common stock to be outstanding after this offering is based on 39,490,161 shares outstanding as of September 29, 2014, and assumes the sale of shares of common stock in this offering.

Unless otherwise indicated, all information in this prospectus, including the number of shares of our common stock to be outstanding after this offering set forth above, excludes the following:

52,829 shares of common stock reserved as of September 29, 2014 for issuance upon any conversion of our Series A Convertible Preferred Stock outstanding as of September 29, 2014;

4,229,913 shares of common stock issuable upon the exercise of stock options at exercise prices ranging from \$0.60 to \$37.50 per share outstanding as of September 29, 2014;

845,900 shares of common stock issuable upon the vesting of outstanding restricted stock units as of September 29, 2014 which vest on dates between June 25, 2015 and June 25, 2018, subject to the fulfillment of services conditions; and

91,251,531 shares of common stock issuable upon the exercise of warrants at exercise prices ranging from \$0.01 to \$1.50 per share.

Unless otherwise indicated, all information in this prospectus assumes no exercise by the underwriters of their over-allotment option.

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## **RISK FACTORS**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below and other information included in this prospectus, including the financial statements and related notes that appear at the end of this prospectus, before deciding to invest in our common stock. These risks should be considered in conjunction with any other information included herein, including in conjunction with forward-looking statements made herein. If any of the following risks actually occur, they could materially adversely affect our business, financial condition, results of operations or prospects. Additional risks and uncertainties that we do not presently know or that we currently deem immaterial may also impair our business, financial condition, results of operations and prospects.*

### **Risks Relating to Our Financial Results and Need for Financing**

#### **We have incurred substantial losses and expect to continue to incur substantial losses over the next few years and we may never become profitable.**

We have never been profitable and we may never become profitable. As of June 30, 2014, we had an accumulated deficit of \$274.0 million. We expect to incur additional losses as we continue our development of bremelanotide, PL-3994 and other product candidates. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital.

We have never had any products available for commercial sale and have received no revenues from the sale of our product candidates. For the foreseeable future, we will have to fund all of our operations and capital expenditures from contract revenue under collaborative development agreements, existing cash balances and outside sources of financing, which may not be available on acceptable terms, if at all. Unless and until we receive approval from the United States Food and Drug Administration, or FDA, or other equivalent regulatory authorities outside the United States, we cannot sell our products and will not have product revenues from them. We have devoted substantially all of our efforts to research and development, including preclinical and clinical trials. Because of the numerous risks associated with developing drugs, we are unable to predict the extent of future losses, whether or when any of our product candidates will become commercially available, or when we will become profitable, if at all.

#### **We have a limited operating history upon which to base an investment decision.**

Our operations are primarily focused on acquiring, developing and securing our proprietary technology, conducting preclinical and clinical studies and formulating and manufacturing on a small-scale basis our principal product candidates. These operations provide a limited basis for stockholders to assess our ability to commercialize our product candidates.

We have not yet demonstrated our ability to perform the functions necessary for the successful commercialization of any of our current product candidates. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

continuing to conduct preclinical development and clinical trials;  
participating in regulatory approval processes;

formulating and manufacturing products, or having third parties formulate and manufacture products;  
post-approval monitoring and surveillance of our products;  
conducting sales and marketing activities, either alone or with a partner; and  
obtaining additional capital.

If we are unable to obtain regulatory approval of any of our product candidates, to successfully commercialize any products for which we receive regulatory approval or to obtain additional capital, we may not be able to recover our investment in our development efforts.

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The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- the ability to raise additional capital on acceptable terms, or at all;
  - timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
  - whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
  - acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
  - our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities, the safety and efficacy of our product candidates or any future product candidates;
  - the prevalence, duration and severity of potential side effects experienced with our product candidates or future approved products, if any;
  - the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
  - achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
  - the ability of third parties with whom we contract to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with GMP;
  - a continued acceptable safety profile and efficacy during clinical development and following approval of our product candidates or any future product candidates;
  - our ability to successfully commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;
  - acceptance by physicians and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
  - our and our partners' ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
  - our and our partners' ability to avoid third-party patent interference or intellectual property infringement claims; and
  - our ability to in-license or acquire additional product candidates or commercial-stage products that we believe can be successfully developed and commercialized.
- If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business.

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**We will need additional financing, including financing to submit required regulatory applications to the FDA for bremelanotide for FSD and to complete clinical trials for our other product candidates, which may be difficult to obtain.**

As of June 30, 2014, we had cash and cash equivalents of \$12.2 million, with current liabilities of \$1.8 million net of unearned revenues of \$1.0 million. In September 2014, we received \$8.8 million pursuant to our agreement with Gedeon Richter to co-develop and commercialize bremelanotide for FSD in the European Union, other European countries and additional selected countries. We believe we have sufficient currently available working capital to fund our planned operations through the quarter ending September 30, 2015, not including initiation of our pivotal Phase 3 clinical trials for bremelanotide for FSD or other planned clinical trials and the proceeds from this offering. Following this offering, assuming the Phase 3 clinical trials of bremelanotide for FSD are successful, as to which there can be no assurance, we will need additional funding to complete submission of required regulatory applications to the FDA for bremelanotide for FSD. We will also need additional funding to complete required clinical trials for our other product candidates and, assuming those clinical trials are successful, as to which there can be no assurance, to complete submission of required regulatory applications to the FDA.

We are preparing to initiate Phase 3 clinical trials of bremelanotide for FSD, and intend to start patient enrollment in the Phase 3 program in the fourth quarter of calendar 2014, but may curtail or delay clinical trial initiation unless we have adequate funds, or commitments for adequate funds, to complete Phase 3 clinical trials. We estimate that the Phase 3 program, including regulatory filings for product approval, will cost at least \$80.0 million. In addition to this offering, we will seek funds to support the Phase 3 program through collaborative arrangements on bremelanotide in addition to our agreement with Gedeon Richter, including marketing and distribution partnering agreements, public or private equity or debt financings, and other sources, but such additional funding may not be available on acceptable terms, or at all.

We do not have any source of significant recurring revenue and must depend on financing or partnering to sustain our operations. We may raise additional funds through public or private equity or debt financings, collaborative arrangements on our product candidates, or other sources. However, additional funding may not be available on acceptable terms, or at all. To obtain additional funding, we may need to enter into arrangements that require us to develop only certain of our product candidates or relinquish rights to certain technologies, product candidates and/or potential markets.

If we are unable to raise sufficient additional funds when needed, we may be required to curtail operations significantly, cease clinical trials and decrease staffing levels. We may seek to license, sell or otherwise dispose of our product candidates, technologies and contractual rights on the best possible terms available. Even if we are able to license, sell or otherwise dispose of our product candidates, technologies and contractual rights, it is likely to be on unfavorable terms and for less value than if we had the financial resources to develop or otherwise advance our product candidates, technologies and contractual rights ourselves.

Our future capital requirements depend on many factors, including:

- the results of our Phase 3 clinical trials for bremelanotide for FSD;
- the timing of, and the costs involved in, obtaining regulatory approvals for bremelanotide for FSD and our other product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;

We will need additional financing, including financing to submit required regulatory applications to the FDA for bremelanotide for FSD and to complete clinical trials for our other product candidates, which may be difficult to obtain.

the scope, progress, results and costs of researching and developing bremelanotide for FSD, PL-3994 or any future product candidates, and conducting preclinical and clinical trials;  
the cost of commercialization activities if bremelanotide for FSD, PL-3994 or any future product candidates are approved for sale, including marketing, sales and distribution costs;  
the cost of manufacturing bremelanotide for FSD, PL-3994 or any future product candidates and any products we successfully commercialize and maintaining our related facilities;

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our ability to establish and maintain strategic collaborations, licensing or other arrangements and the terms and timing of such arrangements;

the degree and rate of market acceptance of any future approved products;

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

any product liability or other lawsuits related to our products;

the expenses needed to attract and retain skilled personnel;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and

the timing, receipt and amount of sales of, or royalties on, future approved products, if any.

**Raising additional capital may cause dilution to existing shareholders, restrict our operations or require us to relinquish rights.**

We may seek the additional capital necessary to fund our operations through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing shareholders' ownership interests will be diluted and the terms may include liquidation or other preferences that adversely affect their rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

## **Risks Related to Our Business, Strategy and Industry**

**We are substantially dependent on the clinical and commercial success of our product candidates, primarily our lead product candidate, bremelanotide for FSD, which is in Phase 3 clinical development. We cannot be certain that we will be able to obtain regulatory approval for or successfully commercialize any of our product candidates.**

To date, we have invested most of our efforts and financial resources in the research and development of bremelanotide for FSD, which is currently our lead product candidate. We are currently in Phase 3 clinical development in the United States for bremelanotide for FSD. Our near-term prospects, including our ability to finance our company and generate revenue, will depend heavily on the successful development, regulatory approval and commercialization of bremelanotide for FSD, as well as any future product candidates. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

timely completion of, or need to conduct additional, clinical trials, including our Phase 3 clinical trials in the United States for bremelanotide for FSD, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the accurate and satisfactory performance of third-party contractors;

our ability to demonstrate to the satisfaction of the FDA the safety and efficacy of bremelanotide for FSD or any future product candidates through clinical trials;

whether we are required by the FDA or other similar foreign regulatory agencies to conduct additional clinical trials to support the approval of bremelanotide for FSD or any future product candidates;

We are substantially dependent on the clinical and commercial success of our product candidates, primarily our lead

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the acceptance of parameters for regulatory approval, including our proposed indication, primary endpoint assessment and primary endpoint measurement, relating to our lead indications of bremelanotide for FSD;  
our success in educating physicians and patients about the benefits, administration and use of bremelanotide for FSD or any future product candidates, if approved;  
the prevalence and severity of adverse events experienced with bremelanotide for FSD or any future product candidates or approved products;  
the adequacy and regulatory compliance of the autoinjector device, supplied by an unaffiliated third party, to be used as part of our bremelanotide combination product;  
the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;  
our ability to raise additional capital on acceptable terms to achieve our goals;  
achieving and maintaining compliance with all regulatory requirements applicable to bremelanotide for FSD or any future product candidates or approved products;  
the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;  
the effectiveness of our own or our future potential strategic collaborators' marketing, sales and distribution strategy and operations;  
our ability to manufacture clinical trial supplies of bremelanotide for FSD or any future product candidates and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or GMP;  
our ability to successfully commercialize bremelanotide for FSD or any future product candidates, if approved for marketing and sale, whether alone or in collaboration with others;  
our ability to enforce our intellectual property rights in and to bremelanotide for FSD or any future product candidates;  
our ability to avoid third-party patent interference or intellectual property infringement claims;  
acceptance of bremelanotide for FSD or any future product candidates, if approved, as safe and effective by patients and the medical community; and  
a continued acceptable safety profile and efficacy of bremelanotide for FSD or any future product candidates following approval.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates.

Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of bremelanotide for FSD or any future product candidate to continue our business.

**Our product candidates are still in the early stages of development and remain subject to clinical testing and regulatory approval. If we are unable to successfully develop and test our product candidates, we will not be successful.**

Our product candidates are at various stages of research and development, will require regulatory approval, and may never be successfully developed or commercialized. Our product candidates will require significant further research, development and testing before we can seek regulatory approval to market and sell them. We must demonstrate that our product candidates are safe and effective for use in patients in order to receive regulatory approval for commercial sale. Preclinical studies in animals, using various doses and formulations, must be performed before we can begin human clinical trials. Even if we obtain favorable results in the preclinical studies, the results in humans may be different. Numerous small-scale human clinical trials may be necessary to obtain initial data on a product candidate's safety and efficacy in humans before advancing to large scale human clinical trials. We face the risk that the results of our trials in later phases of clinical trials

Our product candidates are still in the early stages of development and remain subject to clinical testing and regulatory approval.



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may be inconsistent with those obtained in earlier phases. Adverse or inconclusive results could delay the progress of our development programs and may prevent us from filing for regulatory approval of our product candidates.

Additional factors that could inhibit the successful development of our product candidates include:

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

failure to design appropriate clinical trial protocols;  
uncertainty regarding proper dosing;

inability to develop or obtain a supplier for an autoinjector device that meets the FDA's medical device requirements;  
insufficient data to support regulatory approval;

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

inability to add a sufficient number of clinical trial sites; or

the availability of sufficient capital to sustain operations and clinical trials.

You should evaluate us in light of these uncertainties, difficulties and expenses commonly experienced by early stage biopharmaceutical companies, as well as unanticipated problems and additional costs relating to:

product approval or clearance;

regulatory compliance;

good manufacturing practices;

intellectual property rights;

product introduction; and

marketing and competition.

**If clinical trials for our product candidates are prolonged or delayed, we may be unable to commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any revenue from potential product sales.**

We may be unable to commercialize our product candidates on a timely basis due to unexpected delays in our human clinical trials. Potential delaying events include:

discovery of serious or unexpected toxicities or side effects experienced by study participants or other safety issues;  
slower than expected rates of subject recruitment and enrollment rates in clinical trials resulting from numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same indication, or clinical trials for indications for which patients do not as commonly seek treatment;

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

difficulty in obtaining institutional review board, or IRB, approval for studies to be conducted at each site;

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

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

changes in applicable laws, regulations and regulatory policies;

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delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective contract research organizations, or CROs, clinical trial sites and other third-party contractors;  
failure of our CROs or other third-party contractors to comply with contractual and regulatory requirements or to perform their services in a timely or acceptable manner;  
failure by us, our employees, our CROs or their employees or any partner with which we may collaborate or their employees to comply with applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for drug, medical device and biologic products;  
delays in the scheduling and performance by the FDA of required inspections of us, our CROs, our suppliers, or our clinical trial sites, and violations of law or regulations by discovered in the course of FDA inspections;  
scheduling conflicts with participating clinicians and clinical institutions; or  
difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data.  
Any of these events or other delaying events, individually or in the aggregate, could delay the commercialization of our product candidates and have a material adverse effect on our business, results of operations and financial condition.

**Even if our product candidates receive regulatory approval, they may never achieve market acceptance, in which case our business, financial condition and results of operation will be materially adversely affected.**

Regulatory approval for the marketing and sale of any of our product candidates does not assure the product's commercial success. Any approved product will compete with other products manufactured and marketed by major pharmaceutical and other biotechnology companies. If any of our product candidates are approved by the FDA and do not achieve adequate market acceptance, our business, financial condition and results of operations will be materially adversely affected. The degree of market acceptance of any such product will depend on a number of factors, including:

perceptions by members of the healthcare community, including physicians, about its safety and effectiveness;  
cost-effectiveness relative to competing products and technologies;  
availability of reimbursement for our products from third-party payers such as health insurers, health maintenance organizations and government programs such as Medicare and Medicaid; and  
advantages over alternative treatment methods.

There are currently no FDA approved products for treatment of FSD. As a result, the actual market size and market dynamics are unknown, and there is significant uncertainty concerning the extent and scope of third-party reimbursement for products treating FSD. While we believe that an on-demand drug for FSD has competitive advantages compared to chronic or daily use hormones and other drugs, we may not be able to realize this perceived advantage in the market. Bremelanotide is administered by subcutaneous injection. While the single-use, disposable autoinjector format is designed to maximize market acceptability, bremelanotide as a subcutaneous injectable drug for FSD may never achieve significant market acceptance. In addition, we believe reimbursement of bremelanotide from third-party payers such as health insurers, HMOs or other third-party payers of healthcare costs will be limited, and that the ultimate user will pay all or a substantial part of the cost of bremelanotide for FSD. If the market opportunity for bremelanotide is smaller than we anticipate, it may also be difficult for us to find marketing partners and, as a result, we may be unable to generate revenue and business from bremelanotide. If bremelanotide for FSD does not achieve adequate market acceptance at an acceptable price point, our business, financial condition and results of operations will be materially adversely affected.



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**Even if our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States.**

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others.

Failure to obtain regulatory approval in other countries or any delay or setbacks in obtaining such approval would impair our ability to develop foreign markets for our product candidates and may have a material adverse effect on our results of operations and financial condition.

**If side effects emerge that can be linked to our product candidates that are in development or after they are approved and on the market, we may be required to perform lengthy additional clinical trials, change the labeling of any such products, or withdraw such products from the market, any of which would hinder or preclude our ability to generate revenues.**

If we identify side effects or other problems occur in future clinical trials, we may be required to terminate or delay clinical development of the product candidate. Furthermore, even if any of our product candidates receive marketing approval, as greater numbers of patients use a drug following its approval, if the incidence of side effects increases or if other problems are observed after approval that were not seen or anticipated during pre-approval clinical trials, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to reformulate such products or change the way the product is manufactured;
- we may become the target of lawsuits, including class action suits; and
- our reputation in the market place may suffer resulting in a significant drop in the sales of such products.

Any of these events could substantially increase the costs and expenses of developing, commercializing and marketing any such product candidates or could harm or prevent sales of any approved products.

**The number of subjects in our study pools in our clinical trials may be deemed by regulators to be too small.**

Our clinical trials have been conducted on a pool of subjects that is structured for such research. Nevertheless, there is the possibility that for statistical reasons, the pool of subjects may be determined by the FDA or another regulatory body to be too small to verify statistical significance. In such a case, the conclusions from the previous trials will need to be established with at least another set of clinical trials testing the relevant issue.



**We may not be able to keep up with the rapid technological change in the biotechnology and pharmaceutical industries, which could make any future approved products obsolete and reduce our revenue.**

Biotechnology and related pharmaceutical technologies have undergone and continue to be subject to rapid and significant change. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. In addition, any future products that we develop, including our clinical product candidates, may become obsolete before we recover expenses incurred in developing those products, which may require that we raise additional funds to continue our operations.

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**Competing products and technologies may make our proposed products noncompetitive.**

There are other products being developed for FSD, including flibanserin, a daily-use oral drug being developed for hypoactive sexual desire disorder, and a number of oral combination drugs and daily-use oral and patch drugs incorporating testosterone. There is competition to develop drugs for treatment of FSD in both premenopausal and postmenopausal patients. Ourbremelanotide drug product is intended to be administered by subcutaneous injection, and an on-demand drug product for the same indication which utilizes another route of administration, such as a conventional oral drug product, may make subcutaneousbremelanotide noncompetitive.

There are three oral FDA-approved PDE-5 inhibitor drugs for the treatment of erectile dysfunction, or ED, other approved products and devices for ED, and other products in development for treatment of ED, including products in clinical trials.

There is competition to develop drugs for ED in patients non-responsive to PDE-5 inhibitor drugs, and to develop drugs for treatment of FSD.

There are several products approved for use in treatment of obesity and related indications, and a number of other products being developed for treatment of obesity, including products in clinical trials. There is intense competition to develop drugs for treatment of obesity and related indications.

There are a number of products approved for use in treating inflammatory diseases and dermatologic indication, and other products being developed, including products in clinical trials.

We are aware of one recombinant natriuretic peptide product for acutely decompensated congestive heart failure approved and marketed in the United States, and another recombinant natriuretic peptide product approved and marketed in Japan. Clinical trials on other natriuretic peptide products are being conducted in the United States. In addition, other products for treatment of heart failure are either currently being marketed or in development, including a combination drug which increases active levels of the neuropeptide hormone atrial natriuretic peptide, or ANP.

There are numerous products approved for use in treatment of asthma, and a number of other products being developed for treatment of acute exacerbations of asthma, including products in clinical trials. There is intense competition to develop drugs for treatment of acute exacerbations of asthma.

The biopharmaceutical industry is highly competitive. We are likely to encounter significant competition with respect tobremelanotide, other melanocortin receptor agonist compounds and PL-3994. Most of our competitors have substantially greater financial and technological resources than we do. Many of them also have significantly greater experience in research and development, marketing, distribution and sales than we do. Accordingly, our competitors may succeed in developing, marketing, distributing and selling products and underlying technologies more rapidly than we can. These competitive products or technologies may be more effective and useful or less costly thanbremelanotide, other melanocortin receptor agonist compounds or PL-3994. In addition, academic institutions, hospitals, governmental agencies and other public and private research organizations are also conducting research and may develop competing products or technologies on their own or through strategic alliances or collaborative arrangements.

**We rely on third parties over whom we have no control to conduct clinical trials for our product candidates and their failure to timely perform their obligations could significantly harm our product development.**

We have limited research or development staff and do not have dedicated research or development facilities. We rely on third parties and independent contractors such as researchers at CROs and universities in certain areas that are particularly relevant to our research and product development plans. We engage such researchers to conduct our preclinical studies, clinical trials and associated tests. These outside contractors are not our employees and may terminate their engagements with us at any time. In addition, we have limited control over the resources that these contractors devote to our programs and they may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. There is also competition for these relationships, and we may not be able to maintain our relationships with our contractors on acceptable terms. If our third-party contractors do not carry out their duties under their agreements with us, fail to inform us if our clinical trials fail to comply with clinical trial protocols or fail to

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meet expected deadlines, our ability to develop our product candidates and obtain regulatory approval on a timely basis, if at all, may be materially adversely affected.

**Production and supply of our product candidates depend on contract manufacturers over whom we have no control.**

We do not have the facilities to manufacture bremelanotide, the autoinjector component of our bremelanotide combination product, PL-3994, PL-8177, other melanocortin receptor agonist compounds or our other potential products. Our contract manufacturers must perform these manufacturing activities in a manner that complies with FDA regulations. Our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection. The manufacturers of approved products and their manufacturing facilities will be subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing regulatory requirements, including FDA regulations concerning GMPs. Failure of third-party manufacturers to comply with GMPs, medical device quality systems regulations, or QSR, or other FDA requirements may result in enforcement action by the FDA. Failure to conduct their activities in compliance with FDA regulations could delay our development programs or negatively impact our ability to receive FDA approval of our potential products or continue marketing if they are approved. Establishing relationships with new suppliers, who must be FDA-approved, is a time-consuming and costly process.

**Use of third-party manufacturers may increase the risk that we will not have adequate suppliers of our product candidates or products.**

Reliance on third-party manufacturers entails risk, to which we would not be subject if we manufactured product candidates or products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us; and
- drug product supplies not meeting the requisite requirements for clinical trial use.

If we are not able to obtain adequate supplies of our product candidates, it will be more difficult for us to develop our product candidates and compete effectively. Our product candidates and any products that we and/or our potential future collaborators may develop may compete with other product candidates and products for access to manufacturing facilities.

**We have no experience in marketing, distributing and selling products and will substantially rely on our marketing partners to provide these capabilities.**

We do not have marketing partners for any of our products, including bremelanotide and PL-3994, except that Gedeon Richter is expected to market, or be responsible for marketing, bremelanotide for FSD in Europe and selected other territories. If any of these products are approved by the FDA or other regulatory authorities, we must either develop marketing, distribution and selling capacity and expertise, which will be costly and time consuming, or enter into agreements with other companies to provide these capabilities. We may not be able to enter into suitable agreements on acceptable terms, if at all.

Production and supply of our product candidates depend on contract manufacturers over whom we have ~~no~~ control

**If we are unable to establish sales and marketing capabilities or enter into and maintain agreements with third parties to market and sell our product candidates, we may be unable to generate product revenue.**

We do not currently have an organization nor have any experience in sales, marketing and distribution of pharmaceutical products. We will need to establish sales and marketing capabilities or establish and maintain agreements with third parties to market and sell our product candidates. In order to market any products that may be approved by the FDA or similar foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities, license to a commercial partner, or make arrangements with

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third parties to perform these services. There are risks involved with entering into arrangements with third parties to perform these services, which could delay the commercialization of any of our product candidates, if approved for commercial sale. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and our business would suffer. In addition, if we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we could market and sell any products that we develop ourselves.

**We do not control the development of compounds licensed to third parties and, as a result, we may not realize a significant portion of the potential value of any such license arrangements.**

Under our license, co-development and commercialization agreement with Gedeon Richter for bremelanotide for FSD in a licensed territory, we have limited control over development activities, including regulatory approvals, and no direct control over commercialization efforts. Gedeon Richter may abandon further development of bremelanotide in its licensed territory, including terminating the agreement, for any reason, including a change of priorities within Gedeon Richter or lack of success in clinical trials necessary for obtaining regulatory approvals. Because the potential value of the license arrangement with Gedeon Richter is contingent upon the successful development and commercialization of bremelanotide for FSD in the licensed territory, the ultimate value of this license will depend on the efforts of Gedeon Richter. If Gedeon Richter does not succeed in obtaining regulatory approval of bremelanotide for FSD in the licensed territory for any reason, or does not succeed in securing market acceptance of bremelanotide for FSD in the territory, or elects for any reason to discontinue development of bremelanotide for FSD, we may be unable to realize the potential value of this arrangement.

Under our research collaboration and license agreement with AstraZeneca for melanocortin-based therapeutic compounds for obesity, diabetes and related metabolic syndrome, we have no direct control over the development of compounds and have only limited, if any, input on the direction of development efforts. Based on a serious adverse event, AstraZeneca has decided to discontinue development of AZD2820, a subcutaneously administered peptide melanocortin-4 receptor partial agonist developed during their research collaboration with us. AstraZeneca may decide to abandon further development of this program, including terminating the agreement, if the results of further development efforts are negative or inconclusive, or if priorities within AstraZeneca change, or for any reason.

Because the potential value of the license arrangement with AstraZeneca is contingent upon the successful development and commercialization of the licensed technology, the ultimate value of this license will depend on the efforts of AstraZeneca. If AstraZeneca does not succeed in developing the licensed technology for any reason, or elects for any reason to discontinue the development of this program, we will be unable to realize the potential value of this arrangement.

**Our ability to achieve revenues from the sale of our products in development will depend, in part, on our ability to obtain adequate reimbursement from Medicare, Medicaid, private insurers and other healthcare payers.**

Our ability to successfully commercialize our products in development will depend, in significant part, on the extent to which we or our marketing partners can obtain reimbursement for our products and also reimbursement at appropriate levels for the cost of our products. Obtaining reimbursement from governmental payers, insurance companies, HMOs and other third-party payers of healthcare costs is a time-consuming and expensive process. There is no guarantee that our products will ultimately be reimbursed. There is significant uncertainty concerning third-party reimbursement for the use of any pharmaceutical product incorporating new technology and third-party

We do not control the development of compounds licensed to third parties and, as a result, we may not realize a sig

reimbursement might not be available for our proposed products once approved, or if obtained, might not be adequate.

There are no approved products for treating FSD, and thus there is significant uncertainty concerning the extent and scope of third-party reimbursement for products treating FSD. Based on third-party reimbursement for approved products treating ED, we believe bremelanotide for FSD will be classified as a Tier 3 drug, so that reimbursement will be limited for bremelanotide for treatment of FSD, assuming the product is approved by the FDA. If we are able to obtain reimbursement, continuing efforts by governmental and third-party payers to contain or reduce costs of healthcare may adversely affect our future revenues and ability to achieve profitability. Third-party payers are increasingly challenging the prices charged for diagnostic and therapeutic

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products and related services. Reimbursement from governmental payers is subject to statutory and regulatory changes, retroactive rate adjustments, administrative rulings and other policy changes, all of which could materially decrease the range of products for which we are reimbursed or the rates of reimbursement by government payers. In addition, recent legislation reforming the healthcare system may result in lower prices or the actual inability of prospective customers to purchase our products in development. The cost containment measures that healthcare payers and providers are instituting and the effect of any healthcare reform could materially and adversely affect our ability to operate profitably. Furthermore, even if reimbursement is available, it may not be available at price levels sufficient for us to realize a positive return on our investment, which would have a material adverse effect on our business, financial condition and results of operations.

**Even if we receive regulatory approval for our products in Europe, we may not be able to secure adequate pricing and reimbursement in Europe for us or any strategic partner to achieve profitability.**

Even if one or more of our products are approved in Europe, we may be unable to obtain appropriate pricing and reimbursement for such products. In most European markets, demand levels for healthcare in general and for pharmaceuticals in particular are principally regulated by national governments. Therefore, pricing and reimbursement for our products will have to be negotiated on a Member State by Member State basis according to national rules, as there does not exist a centralized European process. As each Member State has its own national rules governing pricing control and reimbursement policy for pharmaceuticals, there are likely to be uncertainties attaching to the review process, and the level of reimbursement that national governments are prepared to accept. In the current economic environment, governments and private payers or insurers are increasingly looking to contain healthcare costs, including costs on drug therapies. If we are unable to obtain adequate pricing and reimbursement for our products in Europe, we or a potential strategic partner or collaborator may not be able to cover the costs necessary to manufacture, market and sell the product, limiting or preventing our ability to achieve profitability.

**We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.**

The testing and marketing of medical products entails an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products or cease clinical trials. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with corporate collaborators. We currently carry liability insurance as to certain clinical trial risks. We, or any corporate collaborators, may not in the future be able to obtain insurance at a reasonable cost or in sufficient amounts, if at all. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.



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**We are subject to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.**

We are subject to health care fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These health care laws and regulations include, for example:

the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase order or recommendation of, any item or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs;

the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of designated health services with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;

federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us to the extent that our interactions with customers may affect their billing or coding practices; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, and/or exclusion from participation in Medicare, Medi-Cal or other state or federal health care programs, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could have a material adverse effect on our business, results of operations and financial condition.

**We are highly dependent on our management team, senior staff professionals and third-party contractors and consultants, and the loss of their services could materially adversely affect our business.**

We rely on our relatively small management team and staff as well as various contractors and consultants to provide critical services. Our ability to execute our clinical programs for bremelanotide and PL-3994 and our preclinical programs for MC1r and MC4r peptide drug candidates depends on our continued retention and motivation of our management and senior staff professionals, including executive officers and senior members of product development and management who possess significant technical expertise and experience and oversee our development programs.

If we lose the services of existing key personnel, our development programs could be adversely affected if suitable replacement personnel are not recruited quickly. Our success also depends on our ability to develop and maintain relationships with contractors, consultants and scientific advisors.

There is competition for qualified personnel, contractors and consultants in the pharmaceutical industry, which makes it difficult to attract and retain the qualified personnel, contractors and consultants necessary for the development and growth of our business. Our failure to attract and retain such personnel, contractors and consultants could have a

We may incur substantial liabilities and may be required to limit commercialization of our products in response to pro

material adverse effect on our business, results of operations and financial condition.

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**We will need to hire additional employees in order to commercialize our product candidates in the future. Any inability to manage future growth could harm our ability to commercialize our product candidates, increase our costs and adversely impact our ability to compete effectively.**

In order to commercialize our product candidates in the future, we will need to hire experienced sales and marketing personnel to sell and market those product candidates we decide to commercialize, and we will need to expand the number of our managerial, operational, financial and other employees to support commercialization. Competition exists for qualified personnel in the biopharmaceutical field.

Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

**Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.**

Our business, results of operations and financial condition could be adversely affected by general conditions in the global economy and in the global financial markets. Furthermore, the market for FSD may be particularly vulnerable to unfavorable economic conditions. We do not expect bremelanotide for the treatment of FSD to be substantially reimbursed by any government or third-party payer and, as a result, demand for this product will be tied to discretionary spending levels of our targeted patient population. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for bremelanotide for FSD or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

## **Risks Related to Government Regulation**

**Both before and after marketing approval, our product candidates are subject to ongoing regulatory requirements and, if we fail to comply with these continuing requirements, we could be subject to a variety of sanctions and the sale of any approved commercial products could be suspended.**

Both before and after regulatory approval to market a particular product candidate, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising and promotion and record keeping related to the product candidates are subject to extensive regulatory requirements. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

We will need to hire additional employees in order to commercialize our product candidates in the future. Any inability

restrictions on the products or manufacturing process;  
warning letters;  
civil or criminal penalties;  
fines;  
injunctions;

imposition of a Corporate Integrity Agreement, or CIA, requiring heightened monitoring of our compliance functions, overseen by outside monitors, and enhanced reporting requirements to, and oversight by, the FDA and other government agencies;

product seizures or detentions and related publicity requirements;

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suspension or withdrawal of regulatory approvals;  
regulators or IRBs may not authorize us or any potential future collaborators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

total or partial suspension of production; and  
refusal to approve pending applications for marketing approval of new product candidates.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in the regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Even if the FDA approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. The approval may also impose risk evaluation mitigation strategies, or REMS, on a product if the FDA believes there is a reason to monitor the safety of the drug in the marketplace. REMS may include requirements for additional training for health care professionals, safety communication efforts and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMS activities and adjust them if need be. The FDA also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

Furthermore, the approval procedure and the time required to obtain approval varies among countries and can involve additional testing beyond that required by the FDA. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies.

In addition, varying interpretations of the data obtained for preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Even if we submit an application to the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We do not expect to receive regulatory approval for the commercial sale of any of our product candidates that are in development in the near future, if at all. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or any potential future collaborators from commercializing these product candidates in the United States or other countries.

**We may not be able to obtain regulatory approval of bremelanotide for FSD even if the product is effective in treating FSD.**

Clinical drug development programs for our product candidates are very expensive, time-consuming, difficult to design and implement and their outcome is inherently uncertain. Approval of bremelanotide for treatment of FSD in premenopausal women requires a determination by the FDA that the product is both safe and effective. Our Phase 2B clinical trials for FSD demonstrated an acceptable safety profile and, at selected doses, statistically significant efficacy. However, the FDA may ultimately disagree with our definition of efficacy in FSD, our clinical trial designs, or our interpretation of our clinical trial results. Moreover, results obtained in Phase 3 clinical trials may be inconsistent with results obtained in our Phase 2B trials, and may demonstrate either an unacceptable safety profile or insufficient efficacy. It is also possible that safety or efficacy results obtained in Phase 3 clinical trials will be inconclusive. It is not possible to predict, with any assurance, whether the FDA will approve bremelanotide for any indications. The FDA may deny or delay approval of any application for bremelanotide if the FDA determines that the clinical data do not adequately establish the safety of the drug even if efficacy is established. If FDA approves bremelanotide, the approved labeling of the product may be limited or restricted in such ways as to inhibit or prevent

We may not be able to obtain regulatory approval of bremelanotide for FSD even if the product is effective in treating

the successful market acceptance and profitability of the product. Bremelanotide could take a significantly longer time to obtain approval than we expect and it may never gain approval. If regulatory approval of bremelanotide is delayed, limited or never obtained, our business, financial condition and results of operations would be materially adversely affected.

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**The regulatory approval process is lengthy, expensive and uncertain, and may prevent us from obtaining the approvals that we require.**

Government authorities in the United States and other countries extensively regulate the advertising, labeling, storage, record-keeping, safety, efficacy, research, development, testing, manufacture, promotion, marketing and distribution of drug products. Drugs are subject to rigorous regulation in the United States by the FDA and similar regulatory bodies in other countries. The steps ordinarily required by the FDA before a new drug may be marketed in the United States include:

completion of non-clinical tests including preclinical laboratory and formulation studies and animal testing and toxicology;  
submission to the FDA of an Investigational New Drug, or IND, application, which must become effective before clinical trials may begin, and which may be placed on clinical hold by the FDA, meaning the trial may not commence, or must be suspended or terminated prior to completion;  
performance of adequate and well-controlled Phase 1, 2 and 3 human clinical trials to establish the safety and efficacy of the drug for each proposed indication, and potentially post-approval or Phase 4 studies to further define the drug's efficacy and safety, generally or in specific patient populations;  
submission to the FDA of a New Drug Application, or NDA, that must be accompanied by a substantial user fee payment;

FDA review and approval of the NDA before any commercial marketing or sale; and  
compliance with post-approval commitments and requirements.

Satisfaction of FDA pre-market approval requirements for new drugs typically takes a number of years and the actual time required for approval may vary substantially based upon the type, complexity and novelty of the product or disease to be treated by the drug. The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information, demonstrating compliance with applicable GMP requirements. Once the submission has been accepted for filing, the FDA generally has ten months to review the application and respond to the applicant. Such response may be an approval, or may be a complete response letter outlining additional data or steps that must be completed prior to further FDA review of the NDA. The review process is often significantly extended by FDA requests for additional information or clarification. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical trials is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of the advisory committee. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria or if the FDA determines that the clinical data do not adequately establish the safety and efficacy of the drug. Therefore, our proposed products could take a significantly longer time than we expect or may never gain approval. If regulatory approval is delayed or never obtained, our business, financial condition and results of operations would be materially adversely affected.

Some of our products or product candidates, including bremalanotide, may be used in combination with a drug delivery device, such as an injector or other delivery system. Medical products containing a combination of new drugs, biological products or medical devices are regulated as combination products in the United States. A combination product generally is defined as a product comprised of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by the FDA of

The regulatory approval process is lengthy, expensive and uncertain, and may prevent us from obtaining the approvals that we require.

the primary mode of action of the combination product. The determination whether a product is a combination product or two separate products is made by the FDA on a case-by-case basis. Our product candidates intended for use with such devices, or expanded indications that



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we may seek for our products used with such devices, may not be approved or may be substantially delayed in receiving approval if the devices do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval. In addition, because these drug delivery devices are provided by single source unaffiliated third-party companies, we are dependent on the sustained cooperation and effort of those third-party companies both to supply the devices, maintain their own regulatory compliance, and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. We are also dependent on those third-party companies continuing to maintain such approvals or clearances once they have been received. Failure of third-party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices, and maintain compliance with all regulatory requirements, could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications.

Upon approval, a product candidate may be marketed only in those dosage forms and for those indications approved by the FDA. Once approved, the FDA may withdraw the product approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies, referred to as Phase 4 studies, to monitor the approved products in a specific subset of patients or a larger number of patients than were required for product approval and may limit further marketing of the product based on the results of these post-market studies. The FDA has broad post-market regulatory and enforcement powers, including the ability to seek injunctions, levy fines and civil penalties, criminal prosecution, withdraw approvals and seize products or request recalls.

If regulatory approval of any of our product candidates is granted, it will be limited to certain disease states or conditions, patient populations, duration or frequency of use, and will be subject to other conditions as set forth in the FDA-approved labeling. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

Outside the United States, our ability to market our product candidates will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process generally includes all of the risks associated with FDA approval described above. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Community, or EC, registration procedures are available to companies wishing to market a product to more than one EC member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficiency has been presented, a marketing authorization will be granted. If we do not obtain, or experience difficulties in obtaining, such marketing authorizations, our business, financial condition and results of operations may be materially adversely affected.

### **Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of bremelanotide for FSD or any future product candidates and to produce, market and distribute our products after clearance or approval is obtained.**

From time to time, legislation is drafted and introduced in Congress, and court decisions are issued, that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain

revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of bremelanotide for FSD or any future product candidates. We cannot determine what effect changes in regulations, statutes, court decisions, legal interpretation or policies, when and if promulgated, enacted, issued or adopted may have on our business in the future. Such changes could, among other things:

require changes to manufacturing methods;  
require recall, replacement or discontinuance of one or more of our products;

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require additional recordkeeping;  
limit or restrict our ability to engage in certain types of marketing or promotional activities;  
alter or eliminate the scope or terms of any currently available regulatory exclusivities; and  
restrict or eliminate our ability to settle any patent litigation we may bring against potential generic competitors.  
Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition and results of operations.

### **Changes in healthcare policy could adversely affect our business.**

U.S. and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, expanded Medicare coverage for drugs purchased by Medicare beneficiaries and introduced new reimbursement methodologies. In addition, this law provided authority for limiting the number of drugs that will be covered in any therapeutic class. We do not know what impact the MMA and similar laws will have on the availability of coverage for and the price that we receive for any approved products. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare policies in setting their own reimbursement policies, and any reduction in reimbursement that results from the MMA may result in similar reductions by private payers.

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, together the Affordable Care Act or ACA. This law is expected to result in an increase in the number of people who are covered by both public and private insurance and is also expected to substantially change the way health care is financed by both government health program and private insurers, and significantly impact the pharmaceutical industry. The ACA contains a number of provisions that may impact our business and operations in ways that may negatively affect our potential revenues in the future. For example, the ACA imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs which we believe will increase the cost of any products that we develop. Moreover, the ACA established a 2.3% medical device excise tax on certain transactions, including many United States sales of medical devices, which currently includes, and we expect will continue to include, United States sales of drug/device combination products. In addition, as part of the ACA's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the donut hole), we will be required to provide a 50% discount on any branded prescription drugs that we develop sold to beneficiaries who fall within the donut hole. While it is too early to predict all of the specific effects the ACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition.

The availability of government reimbursement for prescription drugs is also likely to be impacted by the Budget Control Act of 2011, which was signed into law on August 2, 2011. This law is expected to result in federal spending cuts totaling between \$1.2 trillion and \$1.5 trillion over the next decade over half of which will include cuts in Medicare and other health related spending.

### **Risks Related to Our Intellectual Property**

**If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish.**

Our success, competitive position and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We cannot predict:

the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;

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if and when patents will be issued;  
whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; and  
whether we will need to initiate litigation or administrative proceedings, which may be costly whether we win or lose.  
If our products, methods, processes and other technologies infringe the proprietary rights of other parties we could incur substantial costs and we may have to:

obtain licenses, which may not be available on commercially reasonable terms, if at all;  
redesign our products or processes to avoid infringement;  
stop using the subject matter claimed in the patents held by others;  
pay damages; or

defend litigation or administrative proceedings, which may be costly whether we win or lose, and which could result in a substantial diversion of our management resources.

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

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation or other proceedings brought at the United States Patent and Trademark Office, or USPTO, may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

**If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.**

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to

infringe or otherwise violate patents owned or controlled by other parties. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

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As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms, if at all.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

**If we are unable to keep our trade secrets confidential, our technologies and other proprietary information may be used by others to compete against us.**

In addition to our reliance on patents, we attempt to protect our proprietary technologies and processes by relying on trade secret laws and agreements with our employees and other persons who have access to our proprietary information. These agreements and arrangements may not provide meaningful protection for our



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proprietary technologies and processes in the event of unauthorized use or disclosure of such information. In addition, our competitors may independently develop substantially equivalent technologies and processes or gain access to our trade secrets or technology, either of which could materially and adversely affect our competitive position.

## **Risks Relating to Obligations in Our 2012 Private Placement**

**Under agreements relating to our 2012 private placement, we are required to allow purchasers in the 2012 private placement to participate in certain future equity and debt financings, which may restrict our ability to raise funds on acceptable terms, or at all.**

For six years after our 2012 private placement, unless the purchasers own less than 20% of our outstanding common stock calculated as if the warrants were exercised, the purchasers have the right of first negotiation on any subsequent equity or debt financing. If we do not agree to terms of a financing with them, and negotiate with a third party on a financing, we must offer to sell to the purchasers at least 55% of the financing, and the purchasers may elect to purchase all or a portion of the financing. We expect that the purchasers will agree to waive their right of first negotiation and right of participation, along with other rights granted to them in the transaction documents for the 2012 private placement, prior to the closing of this offering. We will require significant additional resources and capital for our Phase 3 bremelanotide clinical trial program and other clinical trial programs. The right of first negotiation and right of participation granted to the purchasers in our 2012 private placement may make it more difficult to raise additional funding through public or private equity or debt financings or other sources. Such funding may not be available on acceptable terms, or at all.

**Under agreements relating to our 2012 private placement, so long as any Series A 2012 or Series B 2012 warrants are outstanding, we are required to redeem Series A 2012 and Series B 2012 warrants at the option of the holders in the event of any takeover, change of control or other fundamental transaction which we permit.**

Under the purchase agreement and form of warrants for our 2012 private placement, if we permit, make or allow a takeover, change of control or other fundamental transaction, including any transfer of all or substantially all of our properties or assets, then so long as any warrants remain outstanding we are required, as elected by the warrant holders, to pay such holders a warrant early termination price tied to the greater of the then market price of our common stock or the amount per share paid to any other person. The application of these provisions could adversely affect our financial position and have the effect of delaying or preventing a change of control or other fundamental transaction, which could adversely affect the market price of our common stock, and could make any potential acquisition or change of control more costly.

**Under agreements relating to our 2012 private placement, so long as any Series A 2012 or Series B 2012 warrants are outstanding, we are required to oppose any takeover or change of control that does not provide specified rights to holders of Series A 2012 and Series B 2012 warrants.**

Under the purchase agreement and form of warrants for our 2012 private placement, so long as any warrants remain outstanding we are required to (i) not permit, (ii) take necessary action to prevent both the occurrence or consummation of, and (iii) not be a party to any fundamental transaction, change of control or similar event unless contractually-specified rights are provided with respect to payment of a warrant early termination price tied to the greater of the then market price of our common stock or the amount per share paid to any other person.

We are also required, subject to the exercise by our board of its fiduciary duties, to take all reasonable efforts to adopt a poison pill or any other anti-takeover provision or method necessary to prevent the fundamental transaction, change of control or similar event. The application of these provisions could have the effect of delaying or preventing a change of control or other fundamental transaction, which could adversely affect the market price of our common stock, and could make any potential acquisition or change of control more costly.

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## **Risks Related to this Offering and the Ownership of Our Common Stock**

### **Our stock price is volatile and may fluctuate in a way that is disproportionate to our operating performance and we expect it to remain volatile, which could limit investors' ability to sell stock at a profit.**

The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

publicity regarding actual or potential clinical results relating to products under development by our competitors or us; delay or failure in initiating, completing or analyzing preclinical or clinical trials or unsatisfactory designs or results of these trials;

interim decisions by regulatory agencies, including the FDA, as to clinical trial designs, acceptable safety profiles and the benefit/risk ratio of products under development;

achievement or rejection of regulatory approvals by our competitors or by us;

announcements of technological innovations or new commercial products by our competitors or by us;

developments concerning proprietary rights, including patents;

developments concerning our collaborations;

regulatory developments in the United States and foreign countries;

economic or other crises and other external factors;

period-to-period fluctuations in our revenue and other results of operations;

changes in financial estimates by securities analysts; and

sales of our common stock.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance. If our revenues, if any, in any particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our operating results to suffer further. If our operating results in any future period fall below the expectations of securities analysts or investors, our stock price may fall by a significant amount.

For the 12-month period ended August 31, 2014, the price of our stock has been volatile, ranging from a high of \$1.50 per share to a low of \$0.56 per share. In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

### **Substantial future sales of our shares of common stock in the public market, or the perception that these sales could occur, could cause the price of our common stock to decline.**

Additional sales of our common stock in the public market after this offering, or the perception that these sales could occur, could cause the market price of our common stock to decline. Upon completion of this offering, we will have shares of our common stock outstanding. All shares of common stock sold in this offering will be freely transferable without restriction or additional registration under the U.S. Securities Act of 1933, as amended, or the

Securities Act. The shares of common stock held by our directors, including our officers, will be available for sale upon expiration of a lock-up period, which we expect will expire 90 days after the date of this prospectus. The remaining shares of common stock will be available for sale after this offering since they are not subject to contractual and legal restrictions on resale. Any or all of these shares may be released prior to expiration of the lock-up period at the discretion of the underwriters for this offering.

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To the extent shares are released before the expiration of the lock-up period and these shares are sold into the market, the market price of our common stock could decline.

**As a public company in the United States, we are subject to the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley. We can provide no assurance that we will, at all times, in the future be able to report that our internal controls over financial reporting are effective.**

Companies that file reports with the Securities and Exchange Commission, or the SEC, including us, are subject to the requirements of Section 404 of Sarbanes-Oxley. Section 404 requires management to establish and maintain a system of internal control over financial reporting, and annual reports on Form 10-K filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, must contain a report from management assessing the effectiveness of a company's internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis will be a costly and time-consuming effort that needs to be re-evaluated frequently. Failure on our part to have effective internal financial and accounting controls would cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, and financial condition, and could cause the trading price of our common stock to fall dramatically.

**If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.**

As a smaller company, it may be difficult for us to attract or retain the interest of equity research analysts. A lack of research coverage may adversely affect the liquidity of and market price of our common stock. We do not have any control of the equity research analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company, or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

**Holders of our preferred stock may have interests different from our common stockholders.**

We are permitted under our certificate of incorporation to issue up to 10 million shares of preferred stock. We can issue shares of our preferred stock in one or more series and can set the terms of the preferred stock without seeking any further approval from our common stockholders. 4,697 shares of our Series A Preferred Stock remain outstanding as of September 29, 2014. Each share of Series A Preferred Stock is convertible at any time, at the option of the holder, and such conversion could dilute the value of our common stock to current stockholders and could adversely affect the market price of our common stock. The conversion price decreases if we sell common stock (or equivalents) for a price per share less than the conversion price or less than the market price of the common stock and is also subject to adjustment upon the occurrence of a merger, reorganization, consolidation, reclassification, stock dividend or stock split which results in an increase or decrease in the number of shares of common stock outstanding. Upon (i) liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, (ii) sale or other disposition of all or substantially all of the assets of the Company, or (iii) any consolidation, merger, combination, reorganization

As a public company in the United States, we are subject to the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley. V

or other transaction in which the Company is not the surviving entity or in which the shares of common stock constituting in excess of 50% of the voting power of the Company are exchanged for or changed into other stock or securities, cash and/or any other property, after payment or provision for payment of the debts and other liabilities of the Company, the holders of Series A Preferred Stock will be entitled to receive, pro rata and in preference to the holders of any other capital stock, an amount per share equal to \$100 plus accrued but unpaid dividends, if any. Any preferred stock that we issue may rank ahead of our common stock in terms of dividend priority or liquidation premiums and may have greater voting rights than our common stock.

**Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains.**

We do not anticipate paying any cash dividends in the foreseeable future and intend to retain future earnings, if any, for the development and expansion of our business. Our outstanding Series A Preferred Stock, consisting of 4,697 shares on September 29, 2014, provides that we may not pay a dividend or make any

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distribution to holders of any class of stock unless we first pay a special dividend or distribution of \$100 per share to the holders of the Series A Preferred Stock. In addition, the terms of existing or future agreements may limit our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

**As a new investor, you will experience immediate and substantial dilution as a result of this offering.**

As of June 30, 2014, we had a net book value of approximately \$9.8 million, or \$0.25 per share of common stock, assuming the conversion of all then convertible preferred stock (but excluding the exercise of the warrants issued in our 2012 private placement for 67,476,531 shares issuable at an exercise price of \$0.01 per share and no exercise of any other warrants or options). Based on the public offering price of \$ per share, investors in this offering will experience immediate and substantial dilution of \$ per share in the net book value of the common stock. See Dilution.

**Anti-takeover provisions of Delaware law and our charter documents may make potential acquisitions more difficult and could result in the entrenchment of management.**

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our charter documents may make a change in control or efforts to remove management more difficult. Also, under Delaware law, our board of directors may adopt additional anti-takeover measures. Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in a prescribed manner.

We are authorized to issue up to 300,000,000 shares of common stock. To the extent that we sell or otherwise issue authorized but currently unissued shares, this could have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock.

Our charter authorizes us to issue up to 10,000,000 shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If we exercise this right, it could be more difficult for a third party to acquire a majority of our outstanding voting stock.

In addition, our equity incentive plans generally permit us to accelerate the vesting of options and other stock rights granted under these plans in the event of a change of control. If we accelerate the vesting of options or other stock rights, this action could make an acquisition more costly.

The application of these provisions could have the effect of delaying or preventing a change of control, which could adversely affect the market price of our common stock.

**As of September 29, 2014, there were 96,380,178 shares of common stock underlying outstanding convertible preferred stock, options, restricted stock units and warrants. Stockholders may experience dilution from the conversion of preferred stock, exercise of outstanding options and warrants and vesting**

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital app

**of restricted stock units.**

As of September 29, 2014, holders of our outstanding dilutive securities had the right to acquire the following amounts of underlying common stock:

52,829 shares of common stock reserved for issuance upon any conversion of our Series A Convertible Preferred Stock outstanding as of September 29, 2014;

4,229,913 shares issuable on the exercise of stock options, at exercise prices ranging from \$0.60 to \$37.50 per share;

845,900 shares issuable under restricted stock units which vest on dates between June 25, 2015 and June 25, 2018, subject to the fulfillment of service conditions; and

91,251,531 shares issuable on the exercise of warrants at exercise prices ranging from \$0.01 to \$1.50 per share outstanding as of September 29, 2014.

If the holders convert, exercise or receive these securities, or similar dilutive securities we may issue in the future, stockholders may experience dilution in the net book value of their common stock. In addition, the sale



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or availability for sale of the underlying shares in the marketplace could depress our stock price. We have registered or agreed to register for resale substantially all of the underlying shares listed above. Holders of registered underlying shares could resell the shares immediately upon issuance, which could result in significant downward pressure on our stock price.

**Our failure to meet the continued listing requirements of the NYSE MKT could result in a de-listing of our common stock.**

Our common shares are listed on the NYSE MKT, a national securities exchange, under the symbol PTN . Although we currently meet the NYSE MKT 's listing standards, which generally mandate that we meet certain requirements relating to stockholders ' equity, market capitalization, aggregate market value of publicly held shares and distribution requirements, we cannot assure you that we will be able to continue to meet the NYSE MKT 's listing requirements. If we fail to satisfy the continued listing requirements of the NYSE MKT, such as the corporate governance requirements or the minimum closing bid price requirement, the NYSE MKT may take steps to de-list our common stock. If the NYSE MKT delists our securities for trading on its exchange, we could face significant material adverse consequences, including:

a limited availability of market quotations for our securities;  
reduced liquidity with respect to our securities;

a determination that our shares of common stock are penny stock which will require brokers trading in our shares of common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares of common stock;

a limited amount of news and analyst coverage for our company; and  
a decreased ability to issue additional securities or obtain additional financing in the future.

Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we may take actions to restore our compliance with the NYSE MKT 's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NYSE MKT minimum bid price requirement or prevent future non-compliance with the NYSE MKT 's listing requirements.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as covered securities. Our common shares are considered to be covered securities because they are listed on the NYSE MKT. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if we were no longer listed on the NYSE MKT, our common stock would not be covered securities and we would be subject to regulation in each state in which we offer our securities.

**We will have broad discretion over the use of the proceeds of this offering and may not realize a return.**

Our management will have broad discretion over the use of our net proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment and we might not be able to yield a significant return, if any, on any investment of these net proceeds. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our products and cause the price of our

Our failure to meet the continued listing requirements of the NYSE MKT could result in a de-listing of our 57mmon s

common stock to decline.

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## **SPECIAL NOTE CONCERNING FORWARD-LOOKING STATEMENTS**

This prospectus, including the information that we incorporate by reference, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as believe, will, may, estimate, continue, anticipate, intend, should, plan, potentially or the negative of these terms or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include, but are not limited to, statements concerning the following:

- estimates of our expenses, future revenue, capital requirements;
- our ability to obtain additional financing on terms acceptable to us, or at all;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- the initiation, timing, progress and results of future preclinical studies and clinical trials, and our research and development programs;
- the timing or likelihood of regulatory filings and approvals;
- our expectations regarding the results and the timing of results in our Phase 3 clinical trials of bremelanotide for FSD;
- our expectation regarding the timing of our regulatory submissions for approval of bremelanotide for FSD in the United States and Europe;
- the potential for commercialization of bremelanotide for FSD and other product candidates, if approved, by us;
- our expectations regarding the potential market size and market acceptance for bremelanotide for FSD and our other product candidates, if approved for commercial use;
- our ability to compete with other products and technologies similar to our product candidates;
- the ability of our third-party collaborators to timely carry out their duties under their agreements with us in;
- the ability of our contract manufacturers to perform their manufacturing activities for us in compliance with applicable regulations;
- our ability to recognize the potential value of our licensing arrangements with third parties;
- the potential to achieve revenues from the sale of our product candidates;
- our ability to maintain product liability insurance at a reasonable cost or in sufficient amounts, if at all;
- the retention of key management, employees and third-party contractors;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our compliance with federal and state laws and regulations;
- the timing and costs associated with obtaining regulatory approval for our product candidates;
- the impact of legislative or regulatory healthcare reforms in the United States; and
- our use of proceeds from this offering.

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These forward-looking statements are subject to a number of risks, uncertainties and assumptions described under the section titled **Risk Factors** and elsewhere in this prospectus. We also operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances described in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements contained or incorporated by reference in this prospectus.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, events, circumstances or achievements reflected in the forward-looking statements will ever be achieved or occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus, together with the information incorporated herein by reference as described under the section entitled **Incorporation of Certain Information by Reference**, and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement on Form S-1, of which this prospectus is a part, with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

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## USE OF PROCEEDS

We estimate that the net proceeds from the sale of common stock in this offering will be approximately \$ million, based on an assumed public offering price of \$ per share of common stock, which price was the last reported sale price of our common stock reported on the NYSE MKT on , 2014, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We expect to receive net proceeds of approximately \$ if the underwriters over-allotment option is exercised in full.

We intend to use the net proceeds to us from this offering primarily to advance our Phase 3 clinical trials for our primary product candidate, bremelanotide, which is used for FSD, and secondarily for preclinical and clinical development of our other product candidates and programs, including PL-3994 and MC1r and MC4r programs. The remainder of the net proceeds will be allocated for working capital and other general corporate purposes. Pending use of the net proceeds as described above, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities.

The amounts actually expended for each purpose and the timing of these expenditures may vary significantly depending upon numerous factors, including the amount and timing of the proceeds from this offering. Expenditures will also depend upon the availability of additional financing, whether we are able to enter into an agreement with a development and marketing partner for bremelanotide for FSD in the United States, or PL-3994, MC1r or MC4r in the United States or elsewhere, and if so, the terms and conditions of such agreement, and other factors. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to us from this offering. Accordingly, our management will retain broad discretion as to the allocation of the net proceeds from this offering.

We expect that the proceeds from this offering will be sufficient for us to complete Phase 3 clinical trials for bremelanotide for FSD, but will likely not be sufficient to submit required regulatory applications to the FDA or obtain approval of bremelanotide or any of our other product candidates by the FDA, and we will need significant additional funds in the future. It is also possible that we will not achieve the progress that we expect with respect to clinical trials for bremelanotide for FSD because the actual costs and timing of clinical development activities are difficult to predict and are subject to substantial risks and delays. See the sections entitled Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operation in this prospectus.

TABLE OF CONTENTS**MARKET PRICE OF COMMON STOCK**

Our common stock has been listed on NYSE MKT (formerly NYSE Amex) under the symbol PTN since December 21, 1999. It previously traded on The Nasdaq SmallCap Market under the symbol PLTN. The table below provides, for the fiscal quarters indicated, the reported high and low sales prices for our common stock on the NYSE MKT since July 1, 2012.

	Low	High
Fiscal Year Ending June 30, 2015		
First Quarter (through September 26, 2014)	\$ 0.84	\$ 1.28
Fiscal Year Ended June 30, 2014		
Fourth Quarter	\$ 0.97	\$ 1.43
Third Quarter	0.73	1.50
Second Quarter	0.56	0.83
First Quarter	0.59	0.76
Fiscal Year Ended June 30, 2013		
Fourth Quarter	\$ 0.51	\$ 0.79
Third Quarter	0.54	0.71
Second Quarter	0.53	1.10
First Quarter	0.45	1.20

On September 26, 2014, the closing price as reported on NYSE MKT of our common stock was \$0.87 per share. As of September 29, 2014, we had 94 record holders of our common stock. This number does not include stockholders for whom shares were held in nominee or street name.

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## **DIVIDEND POLICY**

We have never declared or paid any dividends on our common stock. We currently intend to retain earnings, if any, for use in our business. We do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination as to the declaration and payment of dividends on our common stock, if any, will be at the discretion of our board of directors and will depend on then existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. The terms of our outstanding Series A Preferred Stock provide that we may not pay a dividend or make any distribution to holders of any class of our stock unless we first pay a special dividend or distribution of \$100 per share to the holders of the Series A Preferred Stock. As of September 29, 2014, there were 4,697 shares of Series A Preferred Stock outstanding.

TABLE OF CONTENTS**CAPITALIZATION**

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

an actual basis; and  
 an as adjusted basis to give effect to the issuance and sale of shares of our common stock offered by us in this offering at an assumed public offering price of \$ per share, which is the last reported sale price of our common stock as reported on the NYSE MKT on , 2014, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with our financial statements and the related notes appearing at the end of this prospectus and the Management's Discussion and Analysis of Financial Condition and Results of Operations section and other financial information contained in this prospectus.

	As of June 30, 2014	
	Actual	As Adjusted
Cash and cash equivalents	\$ 12,184,605	\$
Stockholders' equity:		
Preferred stock, par value of \$0.01 per share; 10,000,000 shares authorized; Series A Convertible; issued and outstanding 4,697 shares, actual and adjusted	47	
Common stock, par value of \$0.01 per share; 300,000,000 shares authorized; 39,416,595 shares issued and outstanding, actual; shares issued and outstanding, as adjusted	394,166	
Additional paid-in capital	283,428,356	
Accumulated deficit	(274,033,753)	
Total stockholders' equity	\$9,788,816	
Total capitalization	\$9,788,816	

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If you invest in shares of our common stock, your ownership interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the as adjusted net book value per share of our common stock upon closing of this offering. Our historical net book value as of June 30, 2014, was approximately \$9.8 million, or \$0.25 per share of outstanding common stock, based on shares of common stock outstanding as of June 30, 2014. Net book value per share of our common stock is determined at any date by subtracting total liabilities from the amount of total assets, and dividing this amount by the number of shares of common stock deemed to be outstanding as of that date.

After giving effect to the sale by us of      shares of our common stock at a public offering price of \$      per share in connection with this offering, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net book value as of June 30, 2014 would have been approximately \$      million, or approximately \$      per share of outstanding common stock. This amount represents an immediate increase in net book value of \$      per share of our common stock to our existing stockholders and an immediate dilution of \$      per share of our common stock to new investors purchasing securities in this offering, as illustrated in the following table:

Assumed public offering price per share of common stock	\$
Historical net book value per share as of June 30, 2014	\$ 0.25
As adjusted increase in net book value per share attributable to new investors in this offering	\$
As adjusted net book value per share of our common stock after this offering	\$
Dilution of as adjusted net book value per share to new investors	\$

Each \$0.10 increase (decrease) in the public offering price of \$      per share would increase (decrease) our net book value after giving effect to this offering by approximately \$      million, or approximately \$      per share, and the dilution per share to new investors by approximately \$      per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters' over-allotment option is exercised in full, our as adjusted net book value per share after giving effect to this offering would be \$      per share of our common stock, representing an immediate increase in net book value per share to existing stockholders of approximately \$      per share, and an immediate dilution in net book value of \$      per share of our common stock to new investors in this offering would be \$      per share. If any shares of our common stock are issued upon exercise of outstanding options, restricted stock units or warrants or upon conversion of shares of our Series A Preferred Stock, you will experience further dilution.

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

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the Risk Factors section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

## Overview

We are a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. Our programs are based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. Our primary product in clinical development is bremelanotide for the treatment of FSD. In addition, we have drug candidates or development programs for obesity, erectile dysfunction, cardiovascular diseases, pulmonary diseases, inflammatory diseases and dermatologic diseases.

The following drug development programs are actively under development:

Bremelanotide, an on-demand subcutaneous injectable peptide melanocortin receptor agonist, for treatment of FSD in premenopausal women. Bremelanotide, which is a melanocortin agonist, is a synthetic peptide analog of the naturally occurring hormone alpha-MSH. The novel mechanism of action involves activating endogenous melanocortin hormone pathways involved in sexual arousal response. Bremelanotide is scheduled to start Phase 3 clinical trials in the last quarter of calendar 2014;

MC4r compounds for treatment of obesity and diabetes in collaboration with AstraZeneca pursuant to our research collaboration and license agreement. Results of our studies involving MC4r peptides suggest that certain of these peptides may have significant commercial potential for treatment of conditions responsive to MC4r activation, including FSD, ED, obesity and diabetes;

PL-3994, an NPR-A agonist, for treatment of cardiovascular and pulmonary indications. PL-3994 is our lead natriuretic peptide receptor product candidate, and is a synthetic mimetic of the neuropeptide hormone ANP. PL-3994 is in development for treatment of heart failure, acute exacerbations of asthma and refractory hypertension; and MC1r agonist peptides for treatment of inflammatory and dermatologic disease indications. Our MC1r peptide drug candidates are highly specific, with substantially greater binding and efficacy at MC1r than at other melanocortin receptors. We have selected one of our MC1r peptide drug candidates, designated PL-8177, as a clinical trial candidate.

Key elements of our business strategy include: using our technology and expertise to develop and commercialize innovative therapeutic products; entering into alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of product candidates that we are developing; and partially funding our product development programs with the cash flow generated from research collaboration and license agreements and any potential future agreements with third parties.

At June 30, 2014, we had an accumulated deficit of approximately \$274.0 million. We expect to incur substantial operating losses in future periods. We do not expect to generate significant product revenue, sales-based milestones or royalties until we successfully complete development and obtain marketing approval for our product candidates, either alone or in collaborations with third parties, which we expect will take a number of years. In order to commercialize our product candidates, we need to complete clinical development and to comply with comprehensive regulatory requirements.

We believe we have sufficient currently available working capital to fund our planned operations through the quarter ending September 30, 2015, not including initiation of our pivotal Phase 3 clinical trials for

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bremelanotide for FSD or other planned clinical trials. Following this offering, assuming the Phase 3 clinical trials of bremelanotide for FSD are successful, as to which there can be no assurance, we will need additional funding to complete submission of required regulatory applications to the FDA for bremelanotide for FSD. We will also need additional funding to complete required clinical trials for our other product candidates and, assuming those clinical trials are successful, as to which there can be no assurance, to complete submission of required regulatory applications to the FDA. It is possible that we will not achieve the progress that we expect with respect to bremelanotide for FSD because the actual costs and timing of clinical development activities are difficult to predict and are subject to substantial risks and delays. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Financing may not be available to us in the necessary timeframe, in the amounts that we need, on terms acceptable to us, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

## **Critical Accounting Policies and Estimates**

Our significant accounting policies are described in Note 2 to the consolidated financial statements included in this prospectus. We believe that our accounting policies and estimates relating to revenue recognition, accrued expenses and stock-based compensation charges are the most critical.

### **Revenue Recognition**

Revenue from corporate collaborations and licensing agreements consists of up-front fees, research and development funding and milestone payments. Non-refundable up-front fees are deferred and amortized to revenue on a straight-line basis over the related performance period. We estimate the performance period as the period in which we perform certain development activities under the applicable agreement. Reimbursements for research and development activities are recorded in the period that we perform the related activities under the terms of the applicable agreements. Revenue resulting from the achievement of milestone events stipulated in the applicable agreements is recognized when the milestone is achieved, provided that such milestone is substantive in nature.

### **Accrued Expenses**

Third parties perform a significant portion of our development activities. We review the activities performed under significant contracts each quarter and accrue expenses and the amount of any reimbursement to be received from our collaborators based upon the estimated amount of work completed. Estimating the value or stage of completion of certain services requires judgment based on available information. If we do not identify services performed for us but not billed by the service-provider, or if we underestimate or overestimate the value of services performed as of a given date, reported expenses will be understated or overstated.

### **Stock-based Compensation**

The fair value of stock options granted has been calculated using the Black-Scholes option pricing model, which requires us to make estimates of expected volatility and expected option lives. We estimate these factors at the time of grant based on our own prior experience, public sources of information and information for comparable companies.

The amount of recorded compensation related to an option grant is not adjusted for subsequent changes in these estimates or for actual experience. The amount of our recorded compensation is also dependent on our estimates of future option forfeitures. If we initially over-estimate future forfeitures, our reported expenses will be understated until such time as we adjust our estimate. Changes in estimated forfeitures will affect our reported expenses in the period of

change and future periods.

The amount and timing of compensation expense to be recorded in future periods related to grants of restricted stock units may be affected by employment terminations. As a result, stock-based compensation charges may vary significantly from period to period.

## **Preferred Stock and Warrants**

As of June 30, 2014, 4,697 shares of Series A Convertible Preferred Stock were outstanding. Each share of Series A Convertible Preferred Stock is convertible at any time, at the option of the holder, into the number of shares of common stock equal to \$100 divided by the Series A Conversion Price, which, as of June 30, 2014, was \$8.89, so each share of Series A Convertible Preferred Stock was convertible into approximately

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11.25 shares of common stock. In addition, as of June 30, 2014, the Company had outstanding warrants exercisable for 91,583,500 shares of common stock.

## **New Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for us on July 1, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. We are evaluating the effect that ASU 2014-09 will have on our consolidated financial statements and related disclosures. We have not yet determined the effect of the standard on our ongoing financial reporting.

## **Results of Operations**

### **Year Ended June 30, 2014 Compared to the Year Ended June 30, 2013:**

*Revenue* For the fiscal year ended June 30, 2014 (fiscal 2014), we recognized no revenue, compared to \$10,000 for the fiscal year ended June 30, 2013 (fiscal 2013), pursuant to our license agreement with AstraZeneca. Revenue consisted entirely of reimbursement of development costs and per-employee compensation, earned at the contractual rate.

*Research and Development* Research and development expenses were \$10.8 million for fiscal 2014 compared to \$10.5 million for fiscal 2013. Research and development expenses related to our bremelanotide, PL-3994, peptide melanocortin agonist, obesity and other preclinical programs were \$7.9 million and \$7.6 million in fiscal years 2014 and 2013, respectively. The spending was primarily related to the preparation costs of our Phase 3 studies of bremelanotide for the treatment of FSD and secondarily to costs related to our other preclinical and development programs. The amount of such spending and the nature of future development activities are dependent on a number of factors, including primarily the availability of funds to support future development activities, success of our clinical trials and preclinical and discovery programs, and our ability to progress compounds in addition to bremelanotide and PL-3994 into human clinical trials. The amounts of project spending above exclude general research and development spending, which were \$2.9 million for fiscal 2014 and fiscal 2013, respectively.

Cumulative spending from inception to June 30, 2014 on our bremelanotide, NeutroSpec (a previously marketed imaging product which has been terminated) and other programs (which includes PL-3994, PL-8177, other melanocortin receptor agonists, obesity and other discovery programs) amounts to approximately \$170.9 million, \$55.6 million and \$64.5 million, respectively. Due to various risk factors described in this prospectus, including the difficulty in currently estimating the costs and timing of future Phase 1 clinical trials and larger-scale Phase 2 and Phase 3 clinical trials for any product under development, we cannot predict with reasonable certainty when, if ever, a program will advance to the next stage of development or be successfully completed, or when, if ever, related net cash inflows will be generated. See the section entitled Risk Factors in this prospectus.

*General and Administrative* General and administrative expenses were \$5.0 million for fiscal 2014 compared to \$5.1 million for fiscal 2013. These expenses mainly consist of compensation and related costs.

*Other Income (Expense)* Other income (expense) was \$13,000 and \$(7.0) million for fiscal 2014 and fiscal 2013, respectively. For fiscal 2014, we recognized \$19,000 of investment income compared to \$43,000 of investment income for fiscal 2013. Fiscal 2013 other expense included the recognition of \$7.1 million non-cash charged for the increase in the fair value of warrants related to the July 3, 2012 private placement offering from \$0.50 per share at date of issuance to \$0.71 per share upon shareholder approval. Because there were not sufficient authorized shares to cover all the outstanding warrants in the private placement offering as of closing, under ASC 815, Derivatives and Hedging, the portion of the warrants above the then authorized level of common stock was required to be classified as a liability and carried at fair value on our balance sheet. The fair value was calculated by multiplying the number of shares underlying the warrants above the then authorized level of our common stock by the closing price of our common stock less the exercise price of \$0.01 per share. These warrants were liability classified through September 27, 2012, at which time the

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then fair value of the warrant liability was reclassified into stockholders' equity upon stockholder approval of the increase in authorized common stock. There were no warrants required to be liability classified or any changes in fair value of warrants during fiscal 2014.

*Income Tax Benefit* Income tax benefits of \$1.8 million in fiscal 2014 and fiscal 2013, respectively, relate to the sale of New Jersey state net operating loss carryforwards. The amount of such losses and tax credits that we are able to sell depends on annual pools and allocations established by the state of New Jersey. This Program enables approved, unprofitable biotechnology businesses to sell their unused Net Operating Loss Carryovers, or NOLs, and unused Research and Development, or R&D, Tax Credits to unaffiliated, profitable corporate taxpayers in the State of New Jersey.

**Year Ended June 30, 2013 Compared to the Year Ended June 30, 2012:**

*Revenue* For the fiscal year ended June 30, 2013 (fiscal 2013), we recognized \$10,000 in revenue, compared to \$74,000 for the fiscal year ended June 30, 2012 (fiscal 2012), pursuant to our license agreement with AstraZeneca. Revenue consisted entirely of reimbursement of development costs and per-employee compensation, earned at the contractual rate.

*Research and Development* Research and development expenses decreased to \$10.5 million for fiscal 2013 compared to \$13.8 million for fiscal 2012. This decrease was primarily the result of costs relating to our Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for the treatment of FSD.

Research and development expenses related to our bremelanotide, PL-3994, peptide melanocortin agonist, obesity and other preclinical programs were \$7.6 million and \$9.9 million in fiscal years 2013 and 2012, respectively. The majority of spending was related to our Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for the treatment of FSD. The amounts of project spending above exclude general research and development spending, which decreased to \$2.9 million for fiscal 2013 compared to \$3.9 million for fiscal 2012. The decrease was the result of closing our research laboratory operations in connection with the lease expiration of our laboratory facilities in July 2012.

*General and Administrative* General and administrative expenses were \$5.1 million for fiscal 2013 compared to \$5.0 million for fiscal 2012. These expenses mainly consisted of compensation and related costs.

*Other Income (Expense)* Other income (expense) was \$(7.0) million and \$0.5 million for fiscal 2013 and fiscal 2012, respectively. Fiscal 2013 other expense included the recognition of \$7.1 million non-cash charged for the increase in the fair value of warrants related to the July 3, 2012 private placement offering from \$0.50 per share at date of issuance to \$0.71 per share upon shareholder approval. Because there were not sufficient authorized shares to cover all the outstanding warrants in the private placement offering as of closing, under ASC 815, Derivatives and Hedging, the portion of the warrants above the then authorized level of common stock was required to be classified as a liability and carried at fair value on our balance sheet. The fair value was calculated by multiplying the number of shares underlying the warrants above the then authorized level of our common stock by the closing price of our common stock less the exercise price of \$0.01 per share. These warrants were liability classified through September 27, 2012, at which time the then fair value of the warrant liability was reclassified into stockholders' equity upon stockholder approval of the increase in authorized common stock. There were no warrants required to be liability classified or any changes in fair value of warrants during fiscal 2012. Fiscal 2012 other income included a gain on disposition of supplies and equipment of \$0.4 million compared to \$5,000 for fiscal 2013. This increase was a result of closing our research laboratory facilities in July 2012. For fiscal 2013 we recognized \$43,000 of investment income compared to \$32,000 of investment income for fiscal 2012.



*Income Tax Benefit* Income tax benefits of \$1.8 million in fiscal 2013 and \$1.1 million in fiscal 2012 related to the sale of New Jersey state net operating loss carryforwards. The amount of such losses and tax credits that we are able to sell depends on annual pools and allocations established by the state of New Jersey. This Program enables approved, unprofitable biotechnology businesses to sell their unused NOLs and unused R&D Tax Credits to unaffiliated, profitable corporate taxpayers in the State of New Jersey.

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## Liquidity and Capital Resources

Since inception, we have incurred net operating losses, primarily related to spending on our research and development programs. We have financed our net operating losses primarily through equity financings and amounts received under collaborative agreements.

Our product candidates are at various stages of development and will require significant further research, development and testing and some may never be successfully developed or commercialized. We may experience uncertainties, delays, difficulties and expenses commonly experienced by early stage biopharmaceutical companies, which may include unanticipated problems and additional costs relating to:

the development and testing of products in animals and humans;  
product approval or clearance;  
regulatory compliance;  
GMPs;  
intellectual property rights;  
product introduction;  
marketing, sales and competition; and  
obtaining sufficient capital.

Failure to enter into or successfully perform under collaboration agreements and obtain timely regulatory approval for our product candidates and indications would impact our ability to increase revenues and could make it more difficult to attract investment capital for funding our operations. Any of these possibilities could materially and adversely affect our operations and require us to curtail or cease certain programs.

During fiscal 2014, we used \$12.2 million of cash for our operating activities, compared to \$13.6 million used in fiscal 2013 and \$15.5 million used in fiscal 2012. Lower net cash outflows from operations in fiscal 2014 compared to fiscal 2013 were primarily the result of the receipt of a \$1.0 million, non-refundable option fee, relating to a license, co-development and commercialization agreement with Gedeon Richter on bremelanotide for the treatment of FSD in Europe and selected other countries. Lower net cash outflows from operations in fiscal 2013 compared to fiscal 2012 were primarily the result of decreased costs relating to our Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for the treatment of FSD. Our periodic accounts receivable balances will continue to be highly dependent on the timing of receipts from collaboration partners and the division of development responsibilities between us and our collaboration partners.

During fiscal 2014, net cash provided by investing activities was \$5.2 million, which consisted of \$5.2 million of proceeds from the maturity of short-term investments offset by \$6,000 used for capital expenditures. During fiscal 2013, net cash used in investing activities was \$5.3 million, consisting of \$6.0 million used for the purchase of short-term investments and \$60,000 used for capital expenditures offset by the maturity of \$750,000 of short-term investments and \$5,000 in proceeds from the sale of equipment. During fiscal 2012, cash provided by investing activities consisted mainly of \$0.5 million from the sale of supplies and equipment.

During fiscal 2014, cash used in financing activities of \$19,000 consisted of the payment of withholding taxes related to restricted stock units of \$36,000 and payments on capital lease obligation of \$20,000 offset by \$37,500 of proceeds from the exercise of common stock warrants. During fiscal 2013, cash provided by financing activities of \$34.3 million consisted primarily of the net proceeds from the completion of our private placement on July 3, 2012 offset by payments on capital lease obligations of \$22,000 and payment of withholding taxes related to restricted stock units of \$87,000. The private placement consisted of the sale of 3,873,000 shares of our common stock, Series A 2012

warrants to purchase up to 31,988,151 shares of our common stock, and Series B 2012 warrants to purchase up to 35,488,380 shares of our common stock. Aggregate gross proceeds to us were \$35.0 million, with net proceeds, after deducting offering expenses, of \$34.4 million. During fiscal 2012, net cash used in financing activities was \$35,000, consisting entirely of payments on capital lease obligations.

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We have incurred cumulative negative cash flows from operations since our inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. As of June 30, 2014, our cash and cash equivalents were \$12.2 million and our current liabilities were \$1.8 million, net of unearned revenue of \$1.0 million. In September 2014, we received \$8.8 million pursuant to our license, co-development and commercialization agreement with Gedeon Richter on brexelanotide for FSD in Europe and selected countries.

We intend to utilize existing capital resources, including the net proceeds from this offering and approximately \$8.8 million received on execution of our agreement with Gedeon Richter, primarily to advance our Phase 3 clinical trials for our primary product candidate, brexelanotide for FSD, and secondarily for clinical and preclinical development of our other product candidates and programs, including PL-3994 and MC1r and MC4r programs. The remainder of our capital resources will be allocated for general corporate purposes and working capital. We believe that the Phase 3 clinical trial program for brexelanotide, including regulatory filings for product approval, will cost at least \$80.0 million. We are preparing to start patient enrollment in the brexelanotide Phase 3 program in the fourth quarter of calendar 2014, but may curtail or delay clinical trial initiation unless we have adequate funds, or commitments for adequate funds, to complete Phase 3 clinical trials. We intend to seek additional capital to support the Phase 3 program through collaborative arrangements on brexelanotide in addition to our agreement with Gedeon Richter, public or private equity or debt financings, including this offering, or other sources.

We believe that our existing capital resources, together with approximately \$8.8 million received on execution of our agreement with Gedeon Richter, will be adequate to fund our planned operations through the quarter ending September 30, 2015, not including initiation of our pivotal Phase 3 clinical trials for brexelanotide for FSD or other planned clinical trials. Following this offering, assuming the Phase 3 clinical trials of brexelanotide for FSD are successful, as to which there can be no assurance, we will need additional funding to complete submission of required regulatory applications to the FDA for brexelanotide for FSD. We will also need additional funding to complete required clinical trials for our other product candidates and, assuming those clinical trials are successful, as to which there can be no assurance, to complete submission of required regulatory applications to the FDA.

We anticipate incurring additional losses over at least the next few years. To achieve profitability, if ever, we, alone or with others, must successfully develop and commercialize our technologies and proposed products, conduct preclinical studies and clinical trials, obtain required regulatory approvals and successfully manufacture and market such technologies and proposed products. The time required to reach profitability is highly uncertain, and we do not know whether we will be able to achieve profitability on a sustained basis, if at all.

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**Off-Balance Sheet Arrangements**

None.

**Contractual Obligations**

We have entered into various contractual obligations and commercial commitments. The following table summarizes our most significant contractual obligations as of June 30, 2014:

	Payments due by Period				
	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Facility operating leases	\$ 236,355	\$ 236,355			

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## **BUSINESS**

### **Overview**

We are a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. Our programs are based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. Our primary product in clinical development is bremelanotide for the treatment of FSD. In addition, we have drug candidates or development programs for obesity, erectile dysfunction, cardiovascular diseases, pulmonary diseases, inflammatory diseases and dermatologic diseases.

The following drug development programs are actively under development:

Bremelanotide, an on-demand subcutaneous injectable peptide melanocortin receptor agonist, for treatment of FSD in premenopausal women. Bremelanotide, which is a melanocortin agonist, is a synthetic peptide analog of the naturally occurring hormone alpha-MSH. The novel mechanism of action involves activating endogenous melanocortin hormone pathways involved in sexual response. Bremelanotide is scheduled to start Phase 3 clinical trials in the last quarter of calendar 2014;

MC4r compounds for treatment of obesity and diabetes in collaboration with AstraZeneca pursuant to our research collaboration and license agreement. Results of our studies involving MC4r peptides suggest that certain of these peptides may have significant commercial potential for treatment of conditions responsive to MC4r activation, including FSD, ED, obesity and diabetes;

PL-3994, an NPR-A agonist, for treatment of cardiovascular and pulmonary indications. PL-3994 is our lead natriuretic peptide receptor product candidate, and is a synthetic mimetic of the neuropeptide hormone ANP. PL-3994 is in development for treatment of heart failure, acute exacerbations of asthma and refractory hypertension; and MC1r agonist peptides for treatment of inflammatory and dermatologic disease indications. Our MC1r peptide drug candidates are highly specific, with substantially greater binding and efficacy at MC1r than at other melanocortin receptors. We have selected one of our MC1r peptide drug candidates, designated PL-8177, as a clinical trial candidate.

The following chart shows the status of our drug development programs.

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The following table summarizes the projected near-term development milestones on our programs.

MILESTONE	STATUS	TARGETED COMPLETION
Bremelanotide for Female Sexual Dysfunction		
End of Phase 2 and pre-Phase 3 meetings with FDA	Completed	Second quarter, calendar 2014
European rights/collaboration with Gedeon Richter	Completed	Third quarter, calendar 2014
Commence Phase 3 pivotal trials in US	Targeted	Fourth quarter, calendar 2014
U.S. Phase 3 pivotal trial results	Targeted	First half, calendar 2016
Corporate collaboration U.S.	Ongoing discussions	
PL-3994 for Cardiovascular/Pulmonary Indications		
Commence phase 2A clinical trial in HF patients	Targeted	First half, calendar 2015
Corporate collaboration	Targeted	First half, calendar 2015
MC1r Inflammation/Dermatologic Indications		
Clinical development candidate selected	Completed	Second half, calendar 2013
First-in-human clinical trial	Targeted	First half, calendar 2015
Corporate collaboration	Targeted	First half, calendar 2015
AstraZeneca MC4r Development Obesity/Diabetes Program		
Clinical candidate selection	Targeted	First half, calendar 2015
Phase 1 clinical trial	Targeted	Second half, calendar 2015

## Strategy

Key elements of our business strategy include:

Using our technology and expertise to develop and commercialize products in our active drug development programs;  
 Entering into strategic alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of product candidates that we are developing;  
 Partially funding our product development programs with the cash flow generated from research collaboration and license agreements and any potential future agreements with third parties; and  
 Completing development and seeking regulatory approval of bremelanotide for FSD and our other product candidates.

## Our Melanocortin Receptor-Specific Programs

The melanocortin system is involved in a large and diverse number of physiologic functions, and therapeutic agents modulating this system may have the potential to treat a variety of conditions and diseases, including sexual dysfunction, obesity and related disorders, pigmentation disorders and inflammation-related diseases.

**Bremelanotide for FSD.** We are developing subcutaneously administered bremelanotide for the treatment of FSD in premenopausal women. Bremelanotide, which is a melanocortin agonist, is a synthetic peptide analog of the naturally occurring hormone alpha-MSH. The novel mechanism of action involves activating endogenous melanocortin hormone pathways involved in sexual arousal response. We have completed a Phase 2B clinical trial and meetings with the FDA, and are preparing to start patient enrollment in the Phase 3 clinical trials in the fourth quarter of calendar 2014, but may curtail or delay clinical trial initiation unless we have adequate funds, or commitments for adequate funds, to complete the Phase 3 clinical trials.

In August 2014, we entered into an agreement with Gedeon Richter to co-develop and commercialize bremelanotide for FSD in the European Union, other European countries and additional selected countries. Under this agreement we

will contribute, with Gedeon Richter, to the costs of co-development activities for obtaining regulatory approval in Europe. Gedeon Richter will exclusively market bremelanotide for FSD in the licensed territory, and will be responsible for all sales, marketing and commercial activities, including associated costs, in the licensed territory. Gedeon Richter is a European pharmaceutical company with a focus on female healthcare, with \$1.6 billion in sales in 2013, of which \$500 million was in female healthcare.

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We have received €7.5 million (\$9.8 million) in total upfront payments from Gedeon Richter, and will receive a milestone payment of €2.5 million (\$3.3 million) upon the initiation of our Phase 3 clinical trial program in the United States. We have the potential to receive up to €80 million (\$105.6 million) in regulatory and sales related milestones, consisting of \$26.4 million in regulatory milestones and \$79.2 in sales milestones, and low double-digit royalties on net sales in the licensed territory. Our agreement remains in effect as long as Gedeon Richter is selling brexelanotide on which a royalty is owed. The agreement may be terminated by either party upon notice in the event of a material breach or insolvency. In the event Gedeon Richter terminates the agreement because we breached the agreement or are insolvent, Gedeon Richter's license will become fully paid-up, royalty free, perpetual and irrevocable. If Palatin fails to initiate its Phase 3 program by an agreed date, Gedeon Richter at its option may elect to terminate the license and receive a specified payment. In the event that we terminate the agreement because Gedeon Richter breached the agreement or is insolvent, upon timely request all regulatory approvals for brexelanotide in the licensed territory will be transferred to us or our designee.

We are in active discussions with potential partners for U.S. marketing and commercialization rights for brexelanotide. We may not be able to enter into suitable agreements with potential partners on acceptable terms, if at all.

*Phase 2B Clinical Trial Results.* The Phase 2B clinical trial was a multicenter, placebo-controlled, randomized, parallel group, dose-finding trial testing three dose levels, 0.75 mg, 1.25 mg and 1.75 mg, of subcutaneously administered brexelanotide against placebo in premenopausal women diagnosed with hypoactive sexual desire disorder, female sexual arousal disorder or both. The study enrolled 395 premenopausal women across 66 sites within the United States and Canada, with patients randomized to one of three brexelanotide treatment arms and a placebo arm for 16 weeks of treatment. The objective of the Phase 2B trial was to measure safety and efficacy in premenopausal women with hypoactive sexual desire disorder, female sexual arousal disorder or both of brexelanotide compared to placebo. In the Phase 2B trial, subcutaneous doses of brexelanotide and placebo were self-administered by the patient prior to a sexual encounter. The primary efficacy endpoint was change from baseline to end of study in the number of satisfying sexual events, with pre-specified analysis of pooled 1.25 and 1.75 mg doses compared to placebo.

In the Phase 2B clinical trial, the primary endpoint data analysis of 327 pre-menopausal women with hypoactive sexual desire disorder, female sexual arousal disorder or both showed statistically significant and clinically meaningful increases in the number of satisfying sexual events, and statistically significant and clinically meaningful improvement in secondary endpoint measures of overall sexual functioning and distress related to sexual dysfunction, for women taking brexelanotide compared to placebo. Satisfying sexual events were measured with an event log and overall sexual functioning and distress related to sexual dysfunction were measured using validated patient reported outcome measurement tools. Brexelanotide showed a statistically significant increase from baseline in the number of satisfying sexual events compared against placebo at both the 1.75 mg dose and pooled results of the 1.75 and 1.25 mg doses. The mean increase in satisfying sexual events at 1.75 mg dose levels was 0.8 satisfying sexual events per month, from 1.8 to 2.6, with a p value of 0.021 against placebo. For the pooled doses, the mean increase in satisfying sexual events was 0.7 satisfying sexual events per month, from 1.6 to 2.4 (a 50% increase), with a p value of 0.018 against placebo. By contrast, with placebo, the mean change from baseline was from 1.7 to 1.9 (a 12% increase) in satisfying sexual events. The 0.75 mg dose demonstrated a response that was not significant different from placebo.

The mean change from baseline in a validated measurement tool of overall sexual functioning, the Female Sexual Function Index, or FSFI, total score, was 4.4 at the 1.75 mg dose level, compared to 1.88 for placebo, with a p value of 0.0021 against placebo. For the pooled doses, the FSFI total score mean change from baseline was 3.55, compared to 1.88 for placebo, with a p value of 0.0017 against placebo. The FSFI is a 19-item questionnaire measuring improvement in arousal, desire and overall sexual function.

The mean change from baseline in a validated measurement tool of distress related to sexual dysfunction, the Female Sexual Distress Scale-Desire/Arousal/Orgasm, or FSDS-DAO, total score, was -13.1 at the 1.75 mg dose level, compared to -6.8 for placebo, with a p value of 0.0005 against placebo. For the pooled doses, the

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FSDS-DAO total score mean change from baseline was -11.1, compared to -6.8 for placebo, with a p value of 0.036 against placebo. The FSDS-DAO is a 15-item questionnaire that measures personal distress associated with FSD.

A significantly higher percentage of women receiving the 1.75 mg bremelanotide dose, 55%, achieved a clinically meaningful change from baseline of at least one satisfying sexual event compared to 37% of women receiving placebo. In addition, compared against placebo a significantly higher percentage of women also achieved a clinically meaningful improvement in sexual function, as measured by the FSFI (53% vs. 29%), and a clinically meaningful decrease in distress associated with sexual dysfunction as measured by the FSDS-DAO (69% vs. 45%).

Using a validated self-assessment questionnaire of treatment benefit, 79.5% of blinded patients receiving the 1.75 mg dose of bremelanotide reported they benefited from taking the drug, compared to 48.4% of blinded patients receiving placebo.

Bremelanotide was well-tolerated during the Phase 2B clinical trial. The most common types of treatment-emergent adverse events reported more frequently in the bremelanotide arms were facial flushing, nausea, emesis and headache, which were mainly mild-to-moderate in severity. Adverse events that most commonly led to discontinuation were nausea and emesis, with less than 3% discontinuation due to an adverse event. Twenty-six patients, evenly distributed among placebo and active arms of the Phase 2B clinical trial, met the predefined blood pressure withdrawal criteria.

Drug treated patients had approximately a 2 mm Hg change in blood pressure, predominately during the first four hours following dosing. No serious adverse events were attributable to bremelanotide during the trial.

Full data on the Phase 2B clinical trial was presented at the March 2013 annual meeting of the International Society for the Study of Women's Sexual Health.

*Phase 3 Clinical Trial Plans.* We have reached preliminary agreement with the FDA on key aspects of the bremelanotide Phase 3 pivotal registration studies, including FSD patient population, primary and key secondary efficacy endpoints, general study design, dose selection and safety monitoring. In addition, the FDA agreed that the Phase 2 data adequately characterized blood pressure and heart rate signals of bremelanotide, and that standardized methods for in-clinic assessment of blood pressure (a standard blood pressure cuff) would be sufficient for Phase 3. It was also agreed that the intranasal Definitive QTc study was acceptable for NDA submission, as were the carcinogenicity and reproductive toxicity studies. There were no outstanding chemistry, controls or manufacturing issues. Based upon the discussions with the FDA, we have completed

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and expect to submit protocols for the pivotal Phase 3 studies in the third quarter of calendar 2014, have manufactured drug product for clinical trial use and are in the process of negotiating agreements with clinical research organizations and others for Phase 3 studies.

The Phase 3 clinical trials will be conducted in premenopausal women with hypoactive sexual desire disorder, either with or without arousal difficulties, and will include two pivotal double blind placebo-controlled, randomized parallel group trials each with 550 randomized patients in two arms, one a fixed bremelanotide dose and one placebo.

Hypoactive sexual desire disorder is the single largest specific diagnosis in FSD. A 24-week treatment evaluation period will be utilized, with co-primary endpoints of satisfying sexual events and the FSFI desire subdomain (a 28 day recall), and a key secondary endpoint utilizing question 13 of a revised FSDDS questionnaire. Patients in the parallel group trials will have the option, after completion of the trial, to continue in an open-label safety extension study, which will enroll about 600 patients.

Data from the Phase 2B clinical trials from patients diagnosed with the proposed Phase 3 patient population, hypoactive sexual desire disorder or hypoactive sexual desire disorder with female sexual arousal disorder, were analyzed using the Phase 3 clinical trial endpoints of total satisfying sexual events, the FSFI desire subdomain and FSDDS revised question 13. This analysis showed that the 1.75 mg dose was statistically and clinically significant for all three endpoints.

The Phase 3 trials, which will be conducted in North America, will utilize a single-dose autoinjector intended for commercialization. We will also conduct drug interaction and other ancillary studies. It is anticipated that the Phase 3 program will take at least eighteen months from initiation of patient dosing through database lock. Following database lock, clinical trial data will be analyzed and, assuming that we believe the data would support approval of bremelanotide for FSD, an NDA will be submitted to FDA. There can be no assurance that the Phase 3 data will support approval of bremelanotide for FSD or that the FDA will approve an NDA for bremelanotide.

With Gedeon Richter, we met with the European Medicines Agency and received regulatory advice on the Phase 3 clinical data required for approval of bremelanotide for FSD in the European Union. We anticipate that clinical studies will be conducted in Europe, including a pivotal trial with approximately 900 randomized patients which is planned to start in the second half of calendar year 2015.

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The following table summarizes our program timelines for bremelanotide for FSD in the United States and European Union.

MILESTONE	STATUS	TARGETED COMPLETION
In the United States:		
End of Phase 2 and pre-Phase 3 meetings with FDA	Completed	Second quarter, calendar 2014
Final protocols submitted to FDA	Completed	Third quarter, calendar 2014
Commence Phase 3 trials	Targeted	Fourth quarter, calendar 2014
Phase 3 trials results	Targeted	First half, calendar 2016
FDA NDA submission	Targeted	Second half, calendar 2016
FDA approval	Targeted	Second half, calendar 2017
In the European Union:		
European Medicines Agency/CHMP guidance	Completed	First half, calendar 2014
Commence Phase 3 trial	Targeted	Second half, calendar 2015
EU submission	Targeted	Second half, calendar 2017
EU approval	Targeted	Second half, calendar 2018

*Medical Need FSD.* FSD is a multifactorial condition that has anatomical, physiological, medical, psychological and social components, and is defined as persistent or recurring problems during one or more of the stages of sexual response with associated distress. FSD has a significant impact on a patient's self-image, relationships and general well-being. FSD includes four disorders, hypoactive sexual desire disorder, female sexual arousal disorder, sexual pain disorder and orgasmic disorder. Hypoactive sexual desire disorder, either with or without arousal difficulties, is the largest single category of FSD. To establish a diagnosis of FSD, these syndromes must be associated with personal distress, as determined by the affected women. The 2006 PRESIDE study, a cross-sectional, population-based survey of 31,581 female adult respondents in the United States published in 2008 in the journal *Obstetrics & Gynecology*, found that approximately 22% of women reported a sexual problem and 11% were distressed by their sexual problems, with one-third of the women seeking formal care. There are 60 million premenopausal women in the United States according to the 2010 U.S. Census, giving a presenting market size of premenopausal women of about two million. Based on a report by EvaluatePharma, the FSD market is projected to be about \$1.3 billion by 2020.

There are no drugs approved for FSD indications in the United States.

*Subcutaneous Bremelanotide.* Bremelanotide, which is believed to act through activation of melanocortin receptors in the central nervous system, is a first-in-class pharmaceutical agent in development as a treatment of FSD.

Bremelanotide is intended for on-demand use and is self-administered by the patient approximately one hour prior to anticipated sexual activity. We have selected a simple and patient-friendly single dose, disposable autoinjector device which is expected to be used in Phase 3 clinical trials and is intended for commercialization.

*Prior Clinical Trials.* We have completed several Phase 1 clinical studies in which various safety parameters, including blood pressure effects of subcutaneously administered bremelanotide, were studied. Based in part on these studies, our Phase 2B clinical trial assessed the magnitude and duration of blood pressure effect, and determined that subcutaneous administration of selected doses of bremelanotide for treatment of FSD in premenopausal women provides acceptable control of blood pressure effects. We have also completed clinical studies involving an alternative route of administration. Bremelanotide has been evaluated in 31 clinical studies involving about 2,300 subjects, and has shown efficacy in both FSD and ED.

**MC1r Peptide Agonists.** We have initiated preclinical studies with MC1r peptide drug candidates for a number of indications, primarily inflammatory disease-related and autoimmune indications. The MC1r is upregulated in a number of diseases, including inflammatory bowel disease, nephritis, which is inflammation of the kidneys, and rheumatoid arthritis, and ocular indications such as uveitis and dry eye. We believe that MC1r peptides have an anti-inflammatory effect and are involved in regulation of the immune

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system and resolution of pro-inflammatory responses. MC1r peptides also have potential application in a number of dermatologic indications, including vitiligo and erythropoietic protoporphyria.

Our MC1r peptide drug candidates are highly specific, with substantially greater binding and efficacy at MC1r than at other melanocortin receptors. In vitro safety studies have shown that our MC1r peptide drug candidates have no activity in a wide range of various receptors, ion channels and kinases. Our MC1r peptide drug candidates typically have a half-life in animal models of greater than two hours. We have selected one of our MC1r peptide drug candidates, designated PL-8177, as a clinical trial candidate.

Animal studies that we have conducted with our MC1r peptide drug candidates have shown positive results in experimental models of inflammatory bowel disease, uveitis and nephritis. We are continuing to conduct studies on a number of different indications. We have completed preclinical toxicology testing on PL-8177 and chemistry, controls and manufacturing activities to support Phase 1 studies, and anticipate filing an IND application on PL-8177 as early as the fourth quarter of calendar 2014. Contingent on adequate available funds, we anticipate conducting a first-in-man Phase 1 clinical trial in the first half of calendar 2015.

**MC4r Peptide Agonists.** We have developed a series of next generation highly selective MC4r peptides. In developing these peptides, we examined effectiveness in animal models of sexual response and effectiveness in obesity and related metabolic signals, and also determined cardiovascular effects, primarily looking at changes in blood pressure. Results of these studies suggest that certain of these peptides may have significant commercial potential for treatment of conditions responsive to MC4r activation, including FSD, ED, obesity and diabetes. We are engaged in preclinical activities with these peptides, and are evaluating potential pharmaceutical applications.

We have selected an internal lead compound for obesity, designated PL-8905, which has over 100-fold functional selectivity for MC4r over MC1r with minimal effect on blood pressure and limited central nervous system penetration. PL-8905 exhibits chemical and metabolic stability, with a half-life in animal models of greater than two hours. The following graphic illustrates results in a rat model of obesity.

**Obesity Collaboration with AstraZeneca.** In 2007, we entered into an exclusive global research collaboration and license agreement with AstraZeneca to discover, develop and commercialize compounds that target melanocortin receptors for the treatment of obesity, diabetes and related metabolic syndrome. The goal was to design and develop selective MC4r agonists with limited off-target effect, and without toxicities associated with small molecules. In June and December 2008 and in September 2009, the agreement was amended to include additional compounds and associated intellectual property that we developed and to modify royalty rates and milestone payments. Active work under the collaboration portion of the agreement concluded in January 2010.

AstraZeneca initiated human clinical studies with AZD2820, a subcutaneously-administered peptide melanocortin receptor partial agonist that was being developed as a single-agent therapy for the treatment of obesity, but discontinued development after a Phase 1 clinical trial of AZD2820 was halted following a serious adverse event. Based on an investigation, it could not be excluded that the serious adverse event was linked to AZD2820, but it was determined that it was unlikely that the serious adverse event was related to melanocortin agonists as a target for treatment of obesity, and thus was a compound-specific safety concern. AstraZeneca is evaluating its program and next steps. No assurance can be given that AstraZeneca will continue to develop compounds that target melanocortin receptors for the treatment of obesity, diabetes and related metabolic syndrome, or that AstraZeneca will be successful in developing any such compound.





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Obesity is a multifactorial condition with numerous biochemical components relating to satiety (feeling full), energy utilization and homeostasis. A number of different metabolic and hormonal pathways are being evaluated by companies around the world in efforts to develop better treatments for obesity. Scientific research has established that melanocortin receptors have a role in eating behavior and energy homeostasis, and that melanocortin receptor agonists can decrease food intake and induce weight loss.

With AstraZeneca we completed clinical proof-of-concept studies for the MC4r mechanism in obesity, which met the primary objectives of significant decrease in food intake and weight loss.

Our agreement with AstraZeneca remains in effect as long as AstraZeneca is developing a compound covered by the agreement or commercializing a product for which a royalty is owed. The agreement may be terminated by AstraZeneca at any time upon notice to us, or by either party upon notice in the event of a material breach. Upon termination by AstraZeneca without cause or by us for cause, all rights and licenses that we granted to AstraZeneca terminate, but AstraZeneca remains obligated to pay royalties and milestones on compounds developed during the collaboration portion of the agreement. In the event AstraZeneca terminates the agreement because we breached the agreement, rights and licenses that we granted under the agreement become permanent, with financial terms, including royalties, to be determined by arbitration.

We have received up-front payments of \$10 million and milestone payments of \$10 million from AstraZeneca under the agreement. We are eligible for milestone payments totaling up to \$145 million, with up to \$85 million contingent upon development and regulatory milestones and the balance on achievement of sales targets, plus mid to high single digit royalties on sales of approved products. AstraZeneca has responsibility for product commercialization, product discovery and development costs.

**Other Melanocortin Programs.** We are continuing drug discovery efforts in the melanocortin field, primarily developing peptide compounds, including highly selective MC1r agonists and peptides specific for MC4r, including both agonists and antagonists.

## **Our Natriuretic Peptide Receptor-Specific Programs**

The natriuretic peptide receptor system has numerous cardiovascular functions, and therapeutic agents modulating this system may be useful in treatment of heart failure, acute asthma, other pulmonary diseases and hypertension. While the therapeutic potential of modulating this system is well appreciated, development of therapeutic agents has been difficult due, in part, to the short biological half-life of native peptide agonists.

We have designed and are developing candidate drugs that are selective for different natriuretic peptide receptors, including NPR-A, natriuretic peptide receptor B, or NPR-B, natriuretic peptide receptor C, or NPR-C, and both NPR-A and NPR-B.

We are in active discussions with potential partners for marketing and commercialization rights in the United States and the rest of the world for PL-3994 and our related candidate drugs. We may not be able to enter into suitable agreements on acceptable terms with potential partners, if at all.

**PL-3994.** PL-3994 is our lead natriuretic peptide receptor product candidate, and is a synthetic mimetic of the neuropeptide hormone ANP and an NPR-A agonist. PL-3994 is in development for treatment of heart failure, acute exacerbations of asthma and refractory hypertension. PL-3994 activates NPR-A, a receptor known to play a role in cardiovascular homeostasis. Consistent with being an NPR-A agonist, PL-3994 increases plasma cyclic guanosine

monophosphate, or cGMP, levels, a pharmacological response consistent with the effects of endogenous (naturally produced) natriuretic peptides on cardiovascular function and smooth muscle relaxation. PL-3994 also decreases activity of the renin-angiotensin-aldosterone system, or RAAS, a hormone system that regulates blood pressure and fluid balance. The RAAS system is frequently over-activated in heart failure patients, leading to worsening of cardiovascular function. The following graphic illustrates the action of the natriuretic peptide system.

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PL-3994, our lead product development candidate which is ready for Phase 2 safety and efficacy studies, is one of a number of natriuretic peptide receptor agonist compounds we have developed. PL-3994 is a synthetic molecule incorporating a novel and proprietary amino acid mimetic structure, and has an extended circulation half-life and metabolic stability compared to endogenous ANP. Based on the half-life and pharmacokinetics, we believe that PL-3994 is amenable to once daily chronic use subcutaneous administration.

*PL-3994 for Heart Failure.* Heart failure is an illness in which the heart is unable to pump blood efficiently, and includes acutely decompensated heart failure with dyspnea (shortness of breath) at rest or with minimal activity. Endogenous natriuretic peptides have a number of beneficial effects, including vasodilation (relaxation of blood vessels), natriuresis (excretion of sodium) and diuresis (excretion of fluids).

Patients who have been admitted to the hospital with an episode of worsening heart failure have an increased risk of either death or hospital readmission in the three months following discharge. Up to 15% of patients die in this period and as many as 30% need to be readmitted to the hospital. We believe that decreasing mortality and hospital readmission in patients discharged following hospitalization for worsening heart failure is a large unmet medical need for which PL-3994 may be effective. PL-3994 could potentially be utilized as an adjunct to existing heart failure medications, and may, if successfully developed, be self-administered by patients as a subcutaneous injection following hospital discharge. We believe that PL-3994, through activation of NPR-A, may, if successful, reduce cardiac hypertrophy (increase in heart size due to disease), which is an independent risk factor for cardiovascular morbidity and mortality.

Over 5.7 million Americans suffer from heart failure, with 670,000 new cases of heart failure diagnosed each year, with disease incidence expected to increase with the aging of the American population. Heart failure has tremendous human and financial costs. For 2010, the estimated direct costs in the United States for heart failure were \$39.2 billion, with heart failure constituting the leading cause of hospitalization in people over 65 years of age and with over 1.1 million hospital discharges for heart failure in 2006. Of the over 1 million patients hospitalized each year with a primary diagnosis of heart failure, over 50% are readmitted to the hospital within 6 months of discharge. Heart failure is also a high mortality disease, with approximately one-half of heart failure patients dying within five years of initial diagnosis.

Patient populations have been identified which have reduced levels of endogenous active natriuretic peptides, including endogenous active ANP. The reduced levels have a variety of causes, including mutations in endogenous natriuretic peptides and in enzymes necessary to convert natriuretic peptide sequences to their

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active form. Patients with reduced levels of endogenous active natriuretic peptides are reported to have a poor response to current drug therapies and to have increased rates of cardiac remodeling and cardiac events.

We believe that PL-3994 has the potential to treat heart failure with preserved ejection fraction, or HF-PEF, which is a high unmet medical need with no approved treatment options, heart failure with reduced ejection fraction, or HF-REF, and patients with reduced levels of endogenous active natriuretic peptides, such as corin deficiencies, which is a high unmet medical need in patients with a poor response to current therapies, with the objective to restore normal natriuretic peptide function.

We have planned a repeat dose Phase 2 clinical trial in patients with HF-PEF, HF-REF and corin deficiency to evaluate safety profiles and symptom relief as well as pharmacokinetic (period to metabolize or excrete the drug) and pharmacodynamic (period of action or effect of the drug) endpoints. Analysis will include cardiac imaging and measurement of left ventricular ejection fraction. Contingent on adequate available funds, we intend to initiate this trial in the first half of calendar 2015 with data anticipated in the second half of 2015. Assuming favorable results from this trial, we have planned a repeat dose Phase 2 proof-of-principle clinical trial in patients with heart failure, which would involve treatment for a three to six month period, and would evaluate safety, cardiac function, effects on remodeling, symptom improvement and hospitalization admission rates. This trial will be initiated following completion of the first repeat dose Phase 2 clinical trial, with a targeted start of the second half of calendar 2015 with data anticipated by the second half of 2016.

Preclinical studies utilizing a 2 kidney, 1 clip rat model of renovascular hypertension and cardiac hypertrophy have been conducted with PL-3994. Treatment with PL-3994 reduced both excess production of aldosterone and cardiac hypertrophy.

*PL-3994 for Acute Exacerbations of Asthma.* Research over the past two decades has demonstrated potent bronchodilator effects with both systemic and inhalation administration of natriuretic peptides. NPR-A agonism is known to relax smooth muscles in airways and works through a pathway independent of the beta-2 adrenergic receptor. Preclinical testing demonstrated potent airway smooth muscle relaxation in guinea pig and human tissues using PL-3994, and animal studies in sensitized guinea pigs have demonstrated a bronchodilator effect with PL-3994 using both subcutaneous and inhalation administration.

Acute exacerbations of asthma, also called acute severe asthma, is an ongoing, unremitting asthma episode in which asthma symptoms do not adequately respond to initial bronchodilator therapy. Inhaled beta-2 adrenergic receptor agonists, such as albuterol, inhaled anticholinergic drugs, such as ipratropium, and systemic corticosteroids are primary treatments for episodes of acute exacerbations of asthma. Some patients with acute exacerbations of asthma become unresponsive to beta-2 adrenergic receptor agonists, significantly limiting treatment options and increasing risk. Patients who do not respond to initial therapy are at risk of severe complications. We intend to initially target PL-3994 as a treatment for those at-risk unresponsive patients.

Emergency room visits and hospitalizations due to asthma have remained stable from 2001 to 2009, with almost 1.7 million emergency room visits and 440,000 hospitalizations attributed to asthma in 2006. In 2008, approximately 23.3 million Americans had asthma, with a projected 2010 economic cost in the United States of \$20.7 billion, of which the largest single direct medical expenditure, \$5.9 billion, is for prescription drugs.

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Endogenous natriuretic peptides have a very short half-life, due primarily to degradation by neutral endopeptidase and clearance through the natriuretic peptide clearance receptor. PL-3994 is resistant to neutral endopeptidase and clears from the body much more slowly than endogenous natriuretic peptides. PL-3994 has a blood-plasma half-life of at least three hours in humans when administered by subcutaneous injection, with biological effects seen for over eight hours post-administration.

*Clinical Studies with PL-3994.* Human clinical studies of PL-3994 commenced with a Phase 1 trial which concluded in 2008. This was a randomized, double-blind, placebo-controlled study in 26 healthy volunteers who received either PL-3994 or a placebo subcutaneously. The evaluations included safety, tolerability, pharmacokinetics and several pharmacodynamic endpoints, including levels of cGMP, a natural messenger nucleotide. Dosing concluded with the successful achievement of the primary endpoint of the study, a prespecified reduction in systemic blood pressure. No volunteer experienced a serious or severe adverse event. Elevations in plasma cGMP levels, increased diuresis and increased natriuresis were all observed for several hours after single subcutaneous doses.

Later in 2008, we conducted a Phase 2A trial in volunteers with controlled hypertension who were receiving one or more conventional antihypertensive medications. In this trial, which was a randomized, double-blind, placebo-controlled, single ascending dose study in 21 volunteers, the objective was to demonstrate that PL-3994 can be given safely to patients taking antihypertensive medications commonly used in heart failure and hypertension patients. Dosing concluded with the successful achievement of the primary endpoint of the study, a prespecified reduction in systemic blood pressure. No volunteer experienced a serious or severe adverse event. Elevations in plasma cGMP levels were observed for several hours after single subcutaneous doses. Based on the studies to date, PL-3994 is ready for Phase 2 safety and efficacy studies.

*Administration of PL-3994.* For heart failure and refractory hypertension indications we believe that subcutaneous administration of PL-3994 may be preferable. PL-3994 is well absorbed through the subcutaneous route of administration. In human studies, the pharmacokinetic and pharmacodynamic half-lives were on the order of hours, significantly longer than the comparable half-lives of endogenous natriuretic peptides. We believe that subcutaneous PL-3994, if successful, will be amenable to self-administration by patients, similar to insulin and other self-administered drugs. For asthma indications we believe that inhalation administration of PL-3994 may be preferable to subcutaneous or other systemic administration.

## **Technologies We Use**

We used a rational drug design approach to discover and develop proprietary peptide, peptide mimetic and small molecule agonist compounds, focusing on melanocortin and natriuretic peptide receptor systems. Computer-aided drug design models of receptors are optimized based on experimental results obtained with peptides and small molecules that we develop, supported by conformational analyses of peptides in solution utilizing nuclear magnetic resonance spectroscopy. By integrating both technologies, we believe we are developing an advanced understanding of the factors which drive agonism.

We have developed a series of proprietary technologies used in our drug development programs. One technology employs novel amino acid mimetics in place of selected amino acids. These mimetics provide the receptor-binding functions of conventional amino acids while providing structural, functional and physiochemical advantages. The amino acid mimetic technology is employed in PL-3994, our compound in development for treatment of heart failure, acute exacerbations of asthma and refractory hypertension.

Some compound series have been derived using our proprietary and patented platform technology, called MIDAS™, or *Metal Ion-induced Distinctive Array of Structures*. This technology employs metal ions to fix the three-dimensional configuration of peptides, forming conformationally rigid molecules that remain folded specifically in their active state. These MIDAS molecules are generally simple to synthesize, are chemically and proteolytically stable, and have the potential to be orally bioavailable. In addition, MIDAS molecules are information-rich and provide data on structure-activity relationships that may be used to design small molecule, non-peptide drugs.

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## **Estimate of Amount Spent on Research and Development Activities**

Research and development expenses were \$10.8 million for the fiscal year ended June 30, 2014 (fiscal 2014), \$10.5 million for the fiscal year ended June 30, 2013 (fiscal 2013) and \$13.8 million for the fiscal year ended June 30, 2012 (fiscal 2012).

## **Competition**

*General.* Our products under development will compete on the basis of quality, performance, cost effectiveness and application suitability with numerous established products and technologies. We have many competitors, including pharmaceutical, biopharmaceutical and biotechnology companies. Furthermore, there are several well-established products in our target markets that we will have to compete against. Products using new technologies which may be competitive with our proposed products may also be introduced by others. Most of the companies selling or developing competitive products have financial, technological, manufacturing and distribution resources significantly greater than ours and may represent significant competition for us. In addition, if any of our product candidates are approved by FDA, they will eventually face competition from generic versions that will sell at significantly reduced prices, be preferred by managed care and health insurance payers, and be eligible for automatic pharmacy substitution even when a prescriber writes a prescription for our product. The timing and extent of future generic competition is dependent upon both our intellectual property rights and the FDA regulatory process, but cannot be accurately predicted.

The pharmaceutical and biotechnology industries are characterized by extensive research efforts and rapid technological change. Many biopharmaceutical companies have developed or are working to develop products similar to ours or that address the same markets. Such companies may succeed in developing technologies and products that are more effective or less costly than any of those that we may develop. Such companies may be more successful than us in developing, manufacturing and marketing products.

We cannot guarantee that we will be able to compete successfully in the future or that developments by others will not render our proposed products under development or any future product candidates obsolete or non-competitive or that our collaborators or customers will not choose to use competing technologies or products.

*Bremelanotide for Treatment of FSD.* There is competition and financial incentive to develop, market and sell drugs for the treatment of FSD, for which there is no approved drug in the United States. We are aware of several drugs at various stages of development, most of which are taken on a chronic, typically once-daily, basis. Flibanserin, a non-hormone oral serotonin 5-HT<sub>1A</sub> agonist, 5-HT<sub>2A</sub> antagonist that requires chronic dosing, has been investigated for treatment of premenopausal women with hypoactive sexual desire disorder. In the initial submission to FDA, following a negative advisory panel, it was determined that flibanserin failed to meet its co-primary endpoint of daily change of desire. Following two NDA review cycles with the FDA and a formal dispute resolution proceeding, the FDA has required additional safety studies. An oral fixed-dose combination of two antidepressants, bupropion and trazodone, is reported to be entering Phase 2 studies in premenopausal women with hypoactive sexual desire disorder. Another company is developing two different oral fixed-dose combination drugs, one a combination of sildenafil and testosterone and the other a combination of testosterone and buspirone hydrochloride, and is conducting Phase 2 studies in premenopausal women with hypoactive sexual desire disorder. Libigel®, a testosterone gel, completed two Phase 3 efficacy trials for treatment of FSD in surgically post-menopausal women, but did not show statistical separation from placebo in those trials. Intrinsa®, a transdermal testosterone patch, successfully completed a Phase 3

clinical program, but was not approved based on long-term use safety risks of cancer and cardiovascular adverse events. There are other companies reported to be developing new drugs for FSD indications, some of which may be in clinical trials in the United States or elsewhere. We are not aware of any company actively developing a melanocortin receptor agonist drug for FSD.

*PL-3994 for Heart Failure Indications.* Nesiritide (sold under the trade name Natrecor®), a recombinant human B-type natriuretic peptide drug, is marketed in the United States by Scios Inc., a Johnson & Johnson company. Nesiritide is approved for treatment of acutely decompensated congestive heart failure patients who have dyspnea at rest or with minimal activity. Other peptide drugs, including carperitide, a recombinant human atrial natriuretic peptide drug, and ularitide, a synthetic form of urodilatin, a naturally occurring human natriuretic peptide related to atrial natriuretic peptide, have been investigated for treatment of congestive heart failure, but we are not aware of any active development in the United States. We are aware of other



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companies developing intravenously administered natriuretic peptide drugs, with at least one reported to have completed Phase 2 clinical trials for acute heart failure. Novartis AG has reported clinical trial results with a combination drug, LCZ696, which inhibits both the angiotensin II receptor and neprilysin (an enzyme which inactivates endogenous active natriuretic peptides). LCZ696 results in increases of endogenous active ANP levels, and thus has a mechanism of action with similarities to PL-3994. In a Phase 3 trial, LCZ696 was compared to an angiotensin-converting-enzyme inhibitor, enalapril, in heart failure patients with reduced ejection fraction. It significantly improved the rate of death from cardiovascular causes, significantly reduced hospitalization for heart failure and significantly improved heart failure symptoms. LCZ696 clearly demonstrated that upregulation of the natriuretic peptide system in combination with angiotensin-converting-enzyme inhibition is superior to angiotensin-converting-enzyme inhibition alone, and thus provides validation of the natriuretic peptide system as a target for improving outcomes in treating heart failure patients. In addition, there are a number of approved drugs and drugs in development for treatment of heart failure through mechanisms or pathways other than agonism of NPR-A.

*PL-3994 for Acute Exacerbations of Asthma Indications.* The asthma market is intensively competitive, with substantial competition and financial incentive to develop, market and sell drugs for treatment of asthma, with projected costs of prescription drugs of \$5.9 billion in the United States in 2010. We are aware of companies developing drugs for the specific indications of either acute exacerbations of asthma or acute severe asthma, including at least one company with a drug reported to be currently in clinical trials. Certain of these drugs under development work by mechanisms of action different from the mechanisms of action of currently approved products. In addition, a number of clinical trials are conducted by hospitals, research institutes and others exploring various methods and combinations of drugs to treat acute exacerbations of asthma. There are a number of drugs and therapies currently used to treat acute exacerbations of asthma, including administration of oral or intravenous systemic steroids, use of oxygen or heliox, a mixture of helium and oxygen, nebulized short-acting beta-2 adrenergic receptor agonists, intravenous or nebulized anticholinergic agents and, for patients in or approaching respiratory arrest, intubation and mechanical ventilation. However, each of these drugs or therapies has recognized limitations or liabilities, and we believe that there remains an unmet medical need for a safe and effective treatment for acute exacerbations of asthma. We are not aware of any other company actively developing a drug to treat asthma using a natriuretic peptide receptor pathway.

*MC4r Peptides for Erectile Dysfunction.* Leading drugs approved for ED indications are PDE-5 inhibitors which target the vascular system, such as sildenafil (sold under the trade name Viagra®), vardenafil (sold under the trade name Levitra®) and tadalafil (sold under the trade name Cialis®). Other drugs approved for ED indications include alprostadil for injection (sold under the trade name Caverject Impulse® among others), which is injected directly into the penis, and alprostadil in urethral suppository format (sold under the trade name MUSE®). In addition, a variety of devices, including vacuum devices and surgical penile implants, have been approved for ED indications. We are aware of a number of companies developing new drugs for ED indications, some of which are in clinical trials in the United States and elsewhere. We are not aware of any company actively developing a melanocortin receptor agonist drug for ED.

*Obesity.* There are a number of FDA-approved drugs and medical devices for the treatment of obesity, and a large number of products in clinical development by other companies, including products which target melanocortin receptors.

Clinical trials for obesity are lengthy, time-consuming and expensive. See the discussion under the heading "We do not control the development of compounds licensed to third parties and, as a result, we may not realize a significant portion of the potential value of any such license arrangements" in the section titled "Risk Factors" in this prospectus. At least one Phase 2 study has been reported on use of an MC4r agonist for obesity indications.

*MC1r Peptides for Dermatologic and Inflammatory Disease-Related Indications.* Many dermatologic and inflammatory disease-related indications are treated using systemic steroids or immunosuppressant drugs, both of which have side effects which can be dose limiting. There are a large number of approved biological drugs and biological drugs under development for treatment of dermatologic and inflammatory disease-related indications.

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## Patents and Proprietary Information

*Patent Protection.* Our success will depend in substantial part on our ability to obtain, defend and enforce patents, maintain trade secrets and operate without infringing upon the proprietary rights of others, both in the United States and abroad. We own a number of issued United States patents and have pending United States patent applications, many with issued or pending counterpart patents in selected foreign countries. We seek patent protection for our technologies and products in the United States and those foreign countries where we believe patent protection is commercially important.

We own two issued United States patents claiming the bremelanotide substance; issued patents claiming the bremelanotide substance in Australia, Austria, Belgium, Brazil, Canada, Cyprus, Denmark, Finland, France, Germany, Greece, Hong Kong, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, Monaco, Netherlands, New Zealand, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. The issued United States patents have a term until 2020, which term may be subject to extension for a maximum period of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process, pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments). Whether we will be able to obtain patent term extensions under the Hatch-Waxman Amendments and the length of the extension to which we may be entitled cannot be determined until the FDA approves for marketing, if ever, a product in which bremelanotide is the active ingredient. In addition, the claims of issued patents covering bremelanotide may not provide meaningful protection. Further, third parties may challenge the validity or scope of any issued patent, and under the Hatch-Waxman Amendments, potentially receive approval of a competing generic version of our product or products even before a court rules on the validity or infringement of our patents.

We own a patent application pending in the United States and the World Intellectual Property Organization pursuant to the Patent Cooperation Treaty on methods for treating FSD with bremelanotide. We will be required to enter national stage prosecution on this application, including filing the application in countries we select, by May 2015. If any patent issues in the United States, the presumptive term will be until 2033. Whether we will be able to obtain a patent term extension under the Hatch-Waxman Amendments, assuming that a relevant patent issues in the United States, and the length of the extension to which we may be entitled cannot be determined until the FDA approves for marketing, if ever, a product in which bremelanotide is the active ingredient.

We own two issued patents in the United States, Australia, China, Eurasian patent office (for the Russia Federation), and New Zealand claiming an alternative class of melanocortin receptor-specific peptides for treatment of sexual dysfunction, and patent applications on the same class are pending in Brazil, Canada, India, Israel, Japan, Korea, Mexico, and South Africa and before the European patent office. The presumptive term of the patent issued in the United States is until 2029. We also own an issued patent in South Africa and have pending patent applications for a second class of alternative melanocortin receptor-specific peptides for treatment of sexual dysfunction in the United States, Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico, New Zealand and before the European and Eurasian patent offices. If any patent issues in the United States, the presumptive term will be until 2030. Until one or more product candidates covered by a claim of one of these patent applications are developed for commercialization, which may never occur, we cannot evaluate the duration of any potential patent term extension under the Hatch-Waxman Amendments.

We own issued United States and South African patents claiming a narrow class of highly selective MC1r agonist peptides for treatment of inflammation-related diseases and disorders and related indications, and patent applications on two broader classes of highly selective MC1r agonist peptides which are pending in the United States, Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico, and New Zealand and before the European and Eurasian

patent offices. The presumptive term of the patent issued in the United States is until 2030. Until one or more product candidates covered by a claim of one of these patent applications are developed for commercialization, which may never occur, we cannot evaluate the duration of any potential patent term extension under the Hatch-Waxman Amendments.

We own an issued United States patent claiming the PL-3994 substance and other natriuretic peptide receptor agonist compounds that we have developed and an issued United States patent claiming a precursor molecule to the PL-3994 substance, both of which have a term until 2027. Corresponding patents on the PL-3994

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substance and other natriuretic peptide receptor agonist compounds have issued in Australia, Austria, Belgium, China, Colombia, Denmark, Finland, France, Germany, Hong Kong, Hungary, India, Ireland, Israel, Italy, Japan, Mexico, Netherlands, Philippines, Eurasian patent office (for the Russian Federation), South Africa, Spain, Sweden and Switzerland. Patent applications on the PL-3994 substance and other natriuretic peptide receptor agonist compounds are pending in Brazil, Canada, Israel and Korea. Applications claiming precursor molecules for the PL-3994 substance and other compounds have issued in the United States, Australia, France, Germany, India, Ireland, Japan, Mexico, Netherlands, Philippines, Korea, South Africa, Sweden, Switzerland and the United Kingdom. Patent applications on the precursor molecules are pending in Brazil, Canada, China, Hong Kong, Israel and before the Eurasian Patent Office. We also own an issued United States patent claiming use of the PL-3994 substance for treatment of acute asthma and chronic obstructive pulmonary disease, which has a term until 2031. We do not know the full scope of patent coverage we will obtain, or whether any patents will issue other than the patents already issued. Until one or more product candidates covered by a claim of the issued patents or one of these patent applications are developed for commercialization, which may never occur, we cannot evaluate the duration of any potential patent term extension under the Hatch-Waxman Amendments.

We additionally have 29 issued United States patents on melanocortin receptor specific peptides and small molecules, but we are not actively developing any product candidate covered by a claim of any of these patents.

In the event that a third party has also filed a patent application relating to an invention we claimed in a patent application, we may be required to participate in an interference proceeding adjudicated by the United States Patent and Trademark Office to determine priority of invention. The possibility of an interference proceeding could result in substantial uncertainties and cost, even if the eventual outcome is favorable to us. An adverse outcome could result in the loss of patent protection for the subject of the interference, subjecting us to significant liabilities to third parties, the need to obtain licenses from third parties at undetermined cost, or requiring us to cease using the technology.

*Future Patent Infringement.* We do not know for certain that our commercial activities will not infringe upon patents or patent applications of third parties, some of which may not even have been issued. Although we are not aware of any valid United States patents which are infringed by bremelanotide or PL-3994, we cannot exclude the possibility that such patents might exist or arise in the future. We may be unable to avoid infringement of any such patents and may have to seek a license, defend an infringement action, or challenge the validity of such patents in court. Patent litigation is costly and time consuming. If such patents are valid and we do not obtain a license under any such patents, or we are found liable for infringement, we may be liable for significant monetary damages, may encounter significant delays in bringing products to market, or may be precluded from participating in the manufacture, use or sale of products or methods of treatment covered by such patents.

*Proprietary Information.* We rely on proprietary information, such as trade secrets and know-how, which is not patented. We have taken steps to protect our unpatented trade secrets and know-how, in part through the use of confidentiality and intellectual property agreements with our employees, consultants and certain contractors. If our employees, scientific consultants, collaborators or licensees develop inventions or processes independently that may be applicable to our product candidates, disputes may arise about the ownership of proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become our property, but may remain the property of those persons or their employers. Protracted and costly litigation could be necessary to enforce and determine the scope of our proprietary rights.

If trade secrets are breached, our recourse will be solely against the person who caused the secrecy breach. This might not be an adequate remedy to us because third parties other than the person who causes the breach will be free to use the information without accountability to us. This is an inherent limitation of the law of trade secret protection.



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## **U.S. Governmental Regulation of Pharmaceutical Products**

### **General**

Regulation by governmental authorities in the United States and other countries will have a significant impact on our research, product development, manufacturing and marketing of any pharmaceutical products. The nature and the extent to which regulations apply to us will vary depending on the nature of any such products. Our potential pharmaceutical products will require regulatory approval by governmental agencies prior to commercialization. The products we are developing are subject to federal regulation in the United States, principally by the FDA under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and by state and local governments, as well as regulatory and other authorities in foreign governments that include rigorous preclinical and clinical testing and other approval procedures. Such regulations govern or influence, among other things, the research, development, testing, manufacture, safety and efficacy requirements, labeling, storage, recordkeeping, licensing, advertising, promotion, distribution and export of products, manufacturing and the manufacturing process. In many foreign countries, such regulations also govern the prices charged for products under their respective national social security systems and availability to consumers.

All drugs intended for human use are subject to rigorous regulation by the FDA in the United States and similar regulatory bodies in other countries. The steps ordinarily required by the FDA before an innovative new drug product may be marketed in the United States are similar to steps required in most other countries and include, but are not limited to:

- completion of preclinical laboratory tests, preclinical animal testing and formulation studies;
- submission to the FDA of an IND, which must be in effect before clinical trials may commence;
- submission to the FDA of an NDA that includes preclinical data, clinical trial data and manufacturing information;
- payment of substantial user fees for filing the NDA and other recurring user fees;
- FDA review of the NDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities; and
- FDA approval of the NDA, including approval of all product labeling.

For combination products deemed to have a drug primary mode of action, primary review of the product will be conducted by the appropriate division within the Center for Drug Evaluation and Research, or CDER, but CDER will consult with the Center for Devices and Radiological Health, or CDRH, to ensure that the device components of the product meet all applicable device requirements.

The research, development and approval process requires substantial time, effort and financial resources, and approvals may not be granted on a timely or commercially viable basis, if at all.

Preclinical testing includes laboratory evaluations to characterize the product's composition, impurities, stability, and mechanism of its pharmacologic effect, as well as animal studies to assess the potential safety and efficacy of each product. Preclinical safety tests must be conducted by laboratories that comply with FDA regulations regarding Good Laboratory Practices, or GLP, and the U.S. Department of Agriculture's Animal Welfare Act. Violations of these laws and regulations can, in some cases, lead to invalidation of the tests, requiring such tests to be repeated and delaying approval of the NDA. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND and are reviewed by the FDA before the commencement of human clinical trials. Unless the FDA objects to an IND by placing the study on clinical hold, the IND will go into effect 30 days following its receipt by the FDA. The FDA may authorize trials only on specified terms and may suspend ongoing clinical trials at any time on various grounds, including a finding that patients are being exposed to unacceptable

health risks. If the FDA places a study on clinical hold, the sponsor must resolve all of the FDA's concerns before the study may begin or continue. The IND application process may become extremely costly and substantially delay development of products. Similar restrictive requirements also apply in other countries. Additionally, positive results of preclinical tests will not necessarily indicate positive results in clinical trials.



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Clinical trials involve the administration of the investigational product to humans under the supervision of qualified principal investigators. Our clinical trials must be conducted in accordance with Good Clinical Practice, or GCP, regulations under protocols submitted to the FDA as part of an IND. In addition, each clinical trial is approved and conducted under the auspices of an IRB, and requires the patients' informed consent. The IRB considers, among other things, ethical factors, the safety of human subjects, and the possibility of liability of the institutions conducting the trial. The IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for a variety of reasons, including a belief that the test subjects are being exposed to an unacceptable health risk. As the sponsor, we can also suspend or terminate a clinical trial at any time.

Clinical trials are typically conducted in three sequential phases, Phases 1, 2, and 3, involving an increasing number of human subjects. These phases may sometimes overlap or be combined. Phase 1 trials are performed in a small number of healthy human subjects or subjects with the targeted condition, and involve testing for safety, dosage tolerance, absorption, distribution, metabolism and excretion. Phase 2 studies, which may involve up to hundreds of subjects, seek to identify possible adverse effects and safety risks, preliminary information related to the efficacy of the product for specific targeted diseases, dosage tolerance, and optimal dosage. Finally, Phase 3 trials may involve up to thousands of individuals often at geographically dispersed clinical trial sites, and are intended to provide the documentation of effectiveness and important additional safety data required for approval. Prior to commencing Phase 3 clinical trials many sponsors elect to meet with FDA officials to discuss the conduct and design of the proposed trial or trials.

In addition, federal law requires the listing, on a publicly-available website, of detailed information on clinical trials for investigational drugs. Some states have similar or supplemental clinical trial reporting laws.

Success in early-stage animal studies and clinical trials does not necessarily assure success in later-stage clinical trials. Data obtained from animal studies and clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or even prevent regulatory approval.

All data obtained from the preclinical studies and clinical trials, in addition to detailed information on the manufacture and composition of the product, would be submitted in an NDA to the FDA for review and approval for the manufacture, marketing and commercial shipments of any of our products. FDA approval of the NDA is required before commercial marketing or non-investigational interstate shipment may begin in the United States. The FDA may also conduct an audit of the clinical trial data used to support the NDA.

With regard to an NDA, the FDA may deny or delay approval of an application that does not meet applicable regulatory criteria, e.g., if the FDA determines that the preclinical or clinical data or the manufacturing information does not adequately establish the safety and efficacy of the drug. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its NDA. The FDA can request additional information, seek clarification regarding information already provided in the submission or ask that new additional clinical trials be conducted, all of which can delay approval. Similar types of regulatory processes will be encountered as efforts are made to market any drug internationally. We will be required to assure product performance and manufacturing processes from one country to another.

Even if the FDA approves a product, it may limit the approved uses for the product as described in the product labeling, require that contraindications, warning statements or precautions be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a REMS, or otherwise limit the scope of any approval or limit labeling. Once it approves an NDA, the FDA may revoke or suspend the product approval if compliance with post-market regulatory standards is not maintained or if problems occur after the product reaches the

marketplace. In addition, the FDA may require post-marketing studies to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-market studies. The FDA and other government agencies have broad post-market regulatory and enforcement powers, including the ability to levy civil and criminal penalties, suspend or delay issuance of approvals, seize or recall products and revoke approvals.

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Pharmaceutical manufacturers, distributors and their subcontractors are required to register their facilities with the FDA and state agencies, and manufacturers are required to list their marketed drugs with the FDA, and are subject to periodic inspection by the FDA and other authorities, where applicable, and must comply with the FDA's current Good Manufacturing Practices, or GMP, regulations, and the product specifications set forth in the approved NDA. The GMP requirements for pharmaceutical products are extensive and compliance with them requires considerable time, resources and ongoing investment. The regulations require manufacturers and suppliers of raw materials and components to establish validated systems and to employ and train qualified employees to ensure that products meet high standards of safety, efficacy, stability, sterility (where applicable), purity, and potency. The requirements apply to all stages of the manufacturing process, including the synthesis, processing, sterilization, packaging, labeling, storage and shipment of the drug product. For all drug products, the regulations require investigation and correction of any deviations from GMP requirements and impose documentation requirements upon us and any third-party manufacturers that we may decide to use. Manufacturing establishments are subject to mandatory user fees, and to periodic unannounced inspections by the FDA and state agencies for compliance with all GMP requirements. The FDA is authorized to inspect manufacturing facilities without a warrant at reasonable times and in a reasonable manner.

We or our present or future suppliers may not be able to comply with GMP and other FDA regulatory requirements. Failure to comply with the statutory and regulatory requirements subjects the manufacturer and/or the NDA sponsor or distributor to possible legal or regulatory action, such as a delay or refusal to approve an NDA, suspension of manufacturing, seizure or recall of a product, or civil or criminal prosecution of the company or individual officers or employees.

### **Post-Marketing Regulation**

Any drug products manufactured or distributed by us pursuant to FDA approvals, as well as the materials and components used in our products, are subject to pervasive and continuing regulation by the FDA, including:

recordkeeping requirements;

periodic reporting requirements;

GMP requirements related to all stages of manufacturing, testing, storage, packaging, labeling and distribution of finished dosage forms of the product;

monitoring and reporting of adverse experiences with the product; and

advertising and promotional reporting requirements and restrictions.

Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or product removal. Product approvals may be revoked if compliance with regulatory requirements is not maintained or if problems concerning safety or effectiveness of the product occur following approval. The FDA is developing a national electronic drug safety tracking system known as SENTINEL that may impose additional safety monitoring burdens, and enhanced FDA enforcement authority, beyond the extensive requirements already in effect. As a condition of NDA approval, the FDA may require post-approval testing and surveillance to monitor a product's safety or efficacy. The FDA also may impose other conditions, including labeling restrictions which can materially impact the potential market and profitability of a product.

With respect to post-market product advertising and promotion, the FDA and other government agencies including the Department of Health and Human Services and the Department of Justice, and individual States, impose a number of complex regulations on entities that advertise and promote pharmaceuticals, including, among others, standards and restrictions on direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. The FDA has very broad enforcement authority under the FDCA, and failure to abide by these regulations can result in administrative and judicial enforcement actions,

including the issuance of a Warning Letter directing correction of deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, False Claims Act prosecution based on alleged off-label marketing seeking monetary and other penalties, including potential exclusion of the drug and/or the company from participation in government health care programs, and state and federal civil and criminal investigations and prosecutions.

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Foreign regulatory bodies also strictly enforce these and other regulatory requirements and drug marketing may be prohibited in whole or in part in other countries.

We, our collaborators or our third-party contract manufacturers may not be able to comply with the applicable regulations. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems, or the failure to maintain compliance with existing or new regulatory requirements, may result in:

restrictions on the marketing or manufacturing of a product;  
Warning Letters or Untitled Letters from the FDA asking us, our collaborators or third-party contractors to take or refrain from taking certain actions;  
withdrawal of the product from the market;  
the FDA's refusal to approve pending applications or supplements to approved applications;  
voluntary or mandatory product recall;  
fines or disgorgement of profits or revenue;  
suspension or withdrawal of regulatory approvals;  
refusals to permit the import or export of products;  
product seizure; and  
injunctions or the imposition of civil or criminal penalties.

We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition. Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct our business. The laws and regulations that may affect our ability to operate include:

the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs;  
federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the federal civil False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;  
the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business

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

the federal physician sunshine requirements under the Affordable Care Act, which require manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

### **Generic Competition**

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

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify either that: (1) the required patent

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information has not been filed (a Paragraph I Certification); (2) the listed patent has expired (a Paragraph II Certification); (3) the listed patent has not expired, but will expire on a particular date and the generic approval is being sought only after patent expiration (a Paragraph III Certification); or (4) the listed patent is invalid, unenforceable, or will not be infringed by the proposed generic product (a Paragraph IV Certification). In certain circumstances, the ANDA applicant may also elect to submit a section (viii) statement instead of a Paragraph IV Certification, certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the application contains only Paragraph I or Paragraph II Certifications, the ANDA may be approved as soon as FDA completes its review and concludes that all approval requirements have been met. If the ANDA contains one or more Paragraph III Certifications, the ANDA cannot not be approved until each listed patent for which a Paragraph III Certification was filed have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA holder and patent owner once the ANDA has been accepted for filing by the FDA. The patent owner or NDA holder may then commence a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months (the 30-month stay ), expiration of the patent, settlement of the lawsuit in which the patent owner admits that the patent is invalid or not infringed by the ANDA product, or a decision in the infringement case that holds the patent to be invalid or not infringed, or an order by the court shortening the 30-month stay due to actions by the patent holder to delay the litigation. In most circumstances, NDA holder is only eligible for one 30-month stay against an ANDA.

If a patent infringement action is filed against an ANDA applicant, any settlement of the litigation must be submitted to the Federal Trade Commission, or the FTC. If FTC believes the terms or effects of the settlement are anticompetitive, FTC may bring an antitrust enforcement action against the parties. Private parties may also bring antitrust lawsuits against drug companies based on such patent litigation settlements.

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

*Regulatory Exclusivity.* Upon NDA approval of a new chemical entity or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot receive for review any ANDA seeking approval of a generic version of that drug. An ANDA containing a Paragraph IV Certification may be received by FDA 4 years after the NCE drug's approval, but any 30-month stay that ensues would be extended so that it expires seven and one half years after the NCE approval date, subject to early termination by reason of a court decision or settlement as described above.

Certain changes to an NDA drug, such as the addition of a new indication to the package insert, for which new clinical trials, conducted or sponsored by the applicant are deemed by FDA to be essential to the approval of the change, can be eligible for a three-year period of exclusivity during which the FDA cannot approval an ANDA for a generic drug that includes the change. An ANDA that contains a section (viii) statement to a method of use patent may be approved with labeling that omits the patented use before the use patent expires. Generic drugs approved with such a labeling carve out may be substituted by pharmacists for the original branded drug before the method of use patent expires.

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



505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. A 505(b)(2) NDA may be used where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or

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clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication or conditions of use sought by the Section 505(b)(2) applicant.

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

### **Changing Legal and Regulatory Landscape**

Periodically legislation is introduced in the U.S. Congress that could change the statutory and regulatory provisions governing the approval, manufacturing and marketing of our drugs. In addition, the FDCA, FDA regulations and guidance are often revised or reinterpreted by the FDA or the courts in ways that may significantly affect our business and products. We cannot predict whether or when legislation or court decisions impacting our business will be enacted or issued, what FDA regulations, guidance or interpretations may change, or what the impact of such changes, if any, may be in the future.

### **Third-Party Reimbursements**

Successful sales of our proposed products in the United States and other countries depend, in large part, on the availability of adequate reimbursement from third-party payers such as governmental entities, managed care organizations, health maintenance organizations, or HMOs, and private insurance plans. Reimbursement by a third-party payer depends on a number of factors, including the payer's determination that the product has been approved by the FDA for the indication for which the claim is being made, that it is neither experimental nor investigational, and that the use of the product is safe and efficacious, medically necessary, appropriate for the specific patient and cost effective.

Since reimbursement by one payer does not guarantee reimbursement by another, we or our licensees may be required to seek approval from each payer individually. Seeking such approvals is a time-consuming and costly process. Third-party payers routinely limit the products that they will cover and the amount of money that they will pay and, in many instances, are exerting significant pressure on medical suppliers to lower their prices.

Payers frequently employ a tiered system in reimbursing end users for pharmaceutical products, with tier designation affecting copay or deductible amounts. There are no approved products for treating FSD, and thus is significant uncertainty concerning the extent and scope of third-party reimbursement for products treating FSD. Based on third-party reimbursement for approved products treating ED, we believe bremelanotide will be classified as a Tier 3 drug, so that reimbursement will be limited for bremelanotide for treatment of FSD, assuming the product is approved by the FDA. Less than full reimbursement by governmental and other third-party payers may adversely affect the market acceptance of bremelanotide. Further, healthcare reimbursement systems vary from country to country, and third-party reimbursement might not be made available for bremelanotide for FSD under any other reimbursement system.

## **Manufacturing and Marketing**

To be successful, our proposed products will need to be manufactured in commercial quantities under GMPs prescribed by the FDA and at acceptable costs. We do not have the facilities to manufacture any of our proposed products under GMPs. We intend to rely on collaborators, licensees or contract manufacturers for the commercial manufacture of our proposed products.

Our bremelanotide product candidate is a synthetic peptide. While the production process involves well-established technology, there are few manufacturers capable of scaling up to commercial quantities under GMPs at acceptable costs. We have identified one third-party manufacturer for the production of

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bremelanotide, Lonza Ltd., and have validated manufacturing of the bremelanotide drug substance under GMPs with that manufacturer. We are in the process of negotiating a long-term supply agreement with Lonza, and may not be able to enter into a supply agreement on acceptable terms, if at all.

Our bremelanotide product candidate will be a combination product, incorporating both the bremelanotide drug substance and a delivery device. We will rely on a third-party manufacturer, Ypsomed AG, to make the delivery device and to ensure its and the device's continued compliance with all FDA medical device regulations. We have selected an autoinjector delivery device, and are negotiating a long-term supply and manufacturing agreement, but may not be able to enter into such an agreement on acceptable terms, if at all. A third-party contract manufacturer, Catalent Belgium S.A., performs fill, finish and packaging of our bremelanotide product candidate. We are negotiating a long-term commercial supply agreement, but may not be able to enter into such an agreement on acceptable terms, if at all.

Our PL-3994 product candidate is a peptide mimetic molecule, incorporating a proprietary amino acid mimetic structure and amino acids. We identified a manufacturer which made the product in quantities sufficient for Phase 1, and are evaluating commercial-scale manufacturers. Scaling up to commercial quantities may involve production, purification, formulation and other problems not present in the scale of manufacturing done to date.

Our MC1r and MC4r agonist product candidates are synthetic peptides, which we have manufactured only at laboratory scale. We have not contracted with a third-party manufacturer to produce these synthetic peptides for either clinical trials or commercial purposes. While the production process involves well-established technology, there are few manufacturers capable of scaling up to commercial quantities under GMPs at acceptable costs. Additionally, scaling up to commercial quantities may involve production, purification, formulation and other problems not present in the scale of manufacturing done to date.

The failure of any manufacturer or supplier to comply with FDA regulations, including GMPs or medical device QSR, or to supply the device component or drug substance and services as agreed, would force us to seek alternative sources of supply and could interfere with our ability to deliver product on a timely and cost effective basis or at all.

Establishing relationships with new manufacturers or suppliers, any of whom must be FDA-approved, is a time-consuming and costly process.

## **Product Liability and Insurance**

Our business may be affected by potential product liability risks which are inherent in the testing, manufacturing, marketing and use of our proposed products. We have liability insurance providing \$10 million coverage in the aggregate as to certain clinical trial risks.

## **Employees**

As of September 29, 2014, we employed 17 persons full time, of whom 11 are engaged in research and development activities and 6 are engaged in administration and management. While we have been successful in attracting skilled and experienced scientific personnel, competition for personnel in our industry is intense. None of our employees are covered by a collective bargaining agreement. All of our employees have executed confidentiality and intellectual property agreements. We consider relations with our employees to be good.

We rely on contractors and scientific consultants to work on specific research and development programs. We also rely on independent organizations, advisors and consultants to provide services, including aspects of manufacturing,

testing, preclinical evaluation, clinical management, regulatory strategy and market research. Our independent advisors, contractors and consultants sign agreements that provide for confidentiality of our proprietary information and that we have the rights to any intellectual property developed while working for us.

## **Properties**

Our corporate offices are located at 4B Cedar Brook Drive, Cedar Brook Corporate Center, Cranbury, NJ 08512, where we lease approximately 10,000 square feet of office space under a lease that expires in June 2015. The leased property is in good condition.

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## **Legal Proceedings**

We are involved, from time to time, in various claims and legal proceedings arising in the ordinary course of our business. We are not currently a party to any claim or legal proceeding.

## **Corporate Information**

We were incorporated under the laws of the State of Delaware on November 21, 1986 and commenced operations in the biopharmaceutical area in 1996. Our corporate offices are located at 4B Cedar Brook Drive, Cranbury, New Jersey 08512 and our telephone number is (609) 495-2200. We maintain an Internet site at <http://www.palatin.com>, where among other things, we make available free of charge on and through this website our Forms 3, 4 and 5, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) and Section 16 of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our website and the information contained in it or connected to it are not incorporated into this prospectus. The reference to our website is an inactive textual reference only.

TABLE OF CONTENTS**MANAGEMENT****Executive Officers and Directors**

The following table sets forth the names, ages, positions and committee memberships of our directors.

Name	Age	Position with Palatin
Carl Spana, Ph.D.	52	Chief Executive Officer, President and a Director
John K.A. Prendergast, Ph.D. <sup>(3)</sup>	60	Director and Chairman of the Board of Directors
Perry B. Molinoff, M.D. <sup>(1)(3)</sup>	74	Director
Robert K. deVeer, Jr. <sup>(1)(2)</sup>	68	Director
Zola P. Horovitz, Ph.D. <sup>(2)(3)</sup>	79	Director
Robert I. Taber, Ph.D. <sup>(1)(2)</sup>	78	Director
J. Stanley Hull <sup>(2)</sup>	62	Director
Alan W. Dunton, M.D. <sup>(1)(2)</sup>	60	Director
Angela Rossetti <sup>(3)</sup>	61	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

**Carl Spana, Ph.D.**, co-founder of Palatin, has been our chief executive officer and president since June 14, 2000. He has been a director of Palatin since June 1996 and has been a director of our wholly-owned subsidiary, RhoMed Incorporated, since July 1995. From June 1996 through June 14, 2000, Dr. Spana served as an executive vice president and our chief technical officer. From June 1993 to June 1996, Dr. Spana was vice president of Paramount Capital Investments, LLC, a biotechnology and biopharmaceutical merchant banking firm, and of The Castle Group Ltd., a medical venture capital firm. Through his work at Paramount Capital Investments and The Castle Group, Dr. Spana co-founded and acquired several private biotechnology firms. From July 1991 to June 1993, Dr. Spana was a Research Associate at Bristol-Myers Squibb (BMY), a publicly-held pharmaceutical company, where he was involved in scientific research in the field of immunology. He was previously a member of the board of the life science company AVAX Technologies, Inc. (AVXT). Dr. Spana received his Ph.D. in molecular biology from The Johns Hopkins University and his B.S. in biochemistry from Rutgers University. We believe Dr. Spana's qualifications for our board include his leadership experience, business judgment and industry experience. As a senior executive of Palatin for over seventeen years, he provides in-depth knowledge of our company, our drug products under development and the competitive and corporate partnering landscape.

**John K.A. Prendergast, Ph.D.**, co-founder of Palatin, has been chairman of the board since June 14, 2000, and a director since August 1996. Dr. Prendergast has been president and sole stockholder of Summercloud Bay, Inc., an independent consulting firm providing services to the biotechnology industry, since 1993. Dr. Prendergast is a director and executive chairman of the board of directors of Antyra, Inc., a privately-held biopharmaceutical firm. He was previously a member of the board of the life science companies AVAX Technologies, Inc. (AVXT), Avigen, Inc. and MediciNova, Inc. (MNOV). From October 1991 through December 1997, Dr. Prendergast was a managing director of The Castle Group Ltd., a medical venture capital firm. Dr. Prendergast received his M.Sc. and Ph.D. from the University of New South Wales, Sydney, Australia and a C.S.S. in administration and management from Harvard University. We believe Dr. Prendergast brings a historical perspective to our board coupled with extensive industry experience in corporate development and finance in the life sciences field. His prior service on other publicly traded

company boards provides experience relevant to good corporate governance practices.

***Perry B. Molinoff, M.D.*** has been a director since November 2001. He served as our executive vice president for research and development from September 2001 until November 3, 2003, when he resigned to accept a position as Vice Provost for Research at the University of Pennsylvania, which he held from November 2003 through September 2006. He was a director of Cypress Bioscience, Inc., a publicly-held life science company, from 2004 through its acquisition in 2010. In May 2012, he became a director of Cynapsus Therapeutics Inc. (CTE: CTH), a publicly-held Canadian specialty pharmaceutical company. Dr. Molinoff has more than



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30 years of experience in both the industrial and educational sectors. From 1981 to 1994, he was a professor of pharmacology and chairman of the Department of Pharmacology at the University of Pennsylvania School of Medicine in Philadelphia. From January 1995 until March 2001, he was vice president of neuroscience and genitourinary drug discovery for the Bristol-Myers Squibb Pharmaceutical Research Institute, where he was responsible for directing and implementing the Institute's research efforts. Dr. Molinoff earned his medical degree from Harvard Medical School. We believe Dr. Molinoff has extensive academic and pharmaceutical company experience, with scientific knowledge that makes him a resource to our executive officers and other board members. As a former officer of Palatin, Dr. Molinoff has significant knowledge of our technologies and drug products under development, as well as the markets potentially addressed by our drug products under development.

**Robert K. Deveer, Jr.** has been a director since November 1998. Since January 1997, Mr. deVeer has been the president of deVeer Capital LLC, a private investment company. He was a director of Solutia Inc., a publicly-held chemical-based materials company, until its merger with Eastman Chemical Company in July 2012. From 1995 until his retirement in 1996, Mr. deVeer served as Managing Director, Head of Industrial Group, at New York-based Lehman Brothers. From 1973 to 1995, he held increasingly responsible positions at New York-based CS First Boston, including Head of Project Finance, Head of Industrials and Head of Natural Resources. He was a managing director, member of the investment banking committee and a trustee of the First Boston Foundation. He received a B.A. in economics from Yale University and an M.B.A. in finance from Stanford Graduate School of Business. We believe Mr. deVeer has extensive experience in investment banking and corporate finance, including the financing of life sciences companies, and serves as the audit committee's financial expert.

**Zola P. Horovitz, Ph.D.** has been a director since February 2001. Before he retired from Bristol-Myers Squibb (BMS) in 1994, Dr. Horovitz spent 34 years in various positions, including associate director of the Squibb Institute for Medical Research, vice president of development, vice president, scientific liaison, vice president of licensing, and vice president of business development and planning for the pharmaceutical division of Bristol-Myers Squibb (BMS). He held advisory positions at the University of Pittsburgh, Rutgers College of Pharmacy and Princeton University. He is currently a director of GenVec, Inc. (GNVC), a publicly-held life sciences company. Dr. Horovitz previously served on the board of directors of BioCryst Pharmaceutical, Inc. (BCRX), Genaera Corp., Immunicon Corp., NitroMed, Inc., Avigen, Inc. and DOV Pharmaceutical, Inc. Dr. Horovitz earned his Ph.D. in pharmacology from the University of Pittsburgh. We believe Dr. Horovitz has extensive experience in development of pharmaceutical drugs, business development and licensing, and has served on the board of directors of a number of publicly-held life science companies.

**Robert I. Taber, Ph.D.** has been a director since May 2001. Dr. Taber began his career in the pharmaceutical industry in 1962, holding a succession of positions within Schering Corporation's biological research group before leaving in 1982 as director of biological research. He has also held a number of increasingly important positions with DuPont Pharmaceuticals and the DuPont Merck Pharmaceutical Company, including director of pharmaceutical research, director of pharmaceutical and biotechnology research, vice president of pharmaceutical research and vice president of extramural research and development. From 1994 to 1998, Dr. Taber held the position of senior vice president of research and development at Synaptic Pharmaceuticals Corporation before founding Message Pharmaceuticals, Inc. in 1998, serving as president and chief executive officer until 2000. Dr. Taber earned his Ph.D. in pharmacology from the Medical College of Virginia. We believe Dr. Taber has extensive experience in pharmaceutical research and development both in large pharmaceutical companies and in smaller biotechnology and biopharmaceutical companies.

**J. Stanley Hull** has been a director since September 2005. Mr. Hull has over three decades of experience in the field of sales and marketing. Mr. Hull joined Glaxo Smith Kline, a research-based pharmaceutical company, in October 1987 and retired as Senior Vice President, Pharmaceuticals in May 2010, having previously served in the R&D organization of Glaxo Smith Kline (GSK) as Vice President and Worldwide Director of Therapeutic Development and

Product Strategy   Neurology and Psychiatry. Prior to that, he was Vice President of Marketing   Infectious Diseases and Gastroenterology for Glaxo Wellcome Inc. Mr. Hull started his career in the pharmaceutical industry with SmithKline and French Laboratories in 1978. Mr. Hull received his B.S. in business administration from the University of North Carolina at Greensboro. We believe

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Mr. Hull has extensive experience in commercial operations, development and marketing of pharmaceutical drugs and corporate alliances between pharmaceutical companies and biotechnology companies.

**Alan W. Dunton, M.D.** has been a director since June 2011. Since April 2006, he has been president of Danerius, LLC, a biotechnology consulting company, which he founded in 2006. From January 2007 to March 2009, Dr. Dunton served as president and chief executive officer of Panacos Pharmaceuticals Inc. (PANC) and he served as a managing director from March 2009 to January 2011. Dr. Dunton is currently a member of the board of directors of the publicly-traded companies Oragenics, Inc. (OGEN) and Targacept (TRGT), Inc. He previously served on the board of directors of the publicly-traded companies EpiCept Corporation (as Non-Executive Chairman), Adams Respiratory Therapeutics, Inc. (acquired by Reckitt Benckiser Group plc), MediciNova, Inc. (MNOV) and Panacos Pharmaceuticals, Inc. (PANC). Dr. Dunton has served as a director or executive officer of various pharmaceutical companies, and from 1994 to 2001, Dr. Dunton was a senior executive in various capacities in the Pharmaceuticals Group of Johnson & Johnson (JNJ). Dr. Dunton received his M.D. degree from New York University School of Medicine, where he completed his residency in internal medicine. He also was a Fellow in Clinical Pharmacology at the New York Hospital/Cornell University Medical Center. We believe Dr. Dunton has extensive drug development and clinical research experience, having played a key role in the development of more than 20 products to regulatory approval, and also has extensive experience as an executive or officer for large pharmaceutical companies and smaller biotechnology and biopharmaceutical companies.

**Angela Rossetti** has been a director since June 2013. From 2009 through January 2012, she was a vice president at Pfizer Inc. (PFE), where she led a global commercial medicine team for a smoking cessation franchise. She was an assistant vice president at Wyeth, managing a global hemophilia franchise from 2007 until 2009, when Wyeth was acquired by Pfizer, Inc. (PFE). From 2005 to 2006 she was president of Ogilvy Healthworld, an advertising business in the pharmaceutical and biotechnology sectors. Previously, she worked in a variety of increasingly responsible positions in communications, marketing and venture capital/investment banking. Ms. Rossetti is a recent graduate of the Albert Einstein College of Medicine, with a Masters of Bioethics, and has an M.B.A. in Finance from Columbia University Graduate School of Business and a B.A. in Biology from the University of Pennsylvania. We believe Ms. Rossetti has extensive experience in worldwide development and marketing of specialty pharmaceuticals, including prefilled syringe products, and in communications and development of marketing and promotional plans.

Unless a director resigns, all directors hold office until the next annual meeting of stockholders or until their successors have been duly elected and qualified. Directors serve as members of committees as the board determines from time to time.

## **Director Independence**

The board of directors has determined that all of the directors except for Dr. Spana (our chief executive officer and president) are independent directors and committee members, as defined in the NYSE MKT listing standards.

There are no family relationships among any of our directors or executive officers.

## **The Board And Its Committees**

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee.

### *Audit Committee*

The audit committee reviews the engagement of the independent registered public accounting firm and reviews the independence of the independent registered public accounting firm. The audit committee also reviews the audit and non-audit fees of the independent registered public accounting firm and the adequacy of our internal control procedures. The audit committee is currently composed of four non-employee directors, Mr. deVeer (chair) and Drs. Taber, Molinoff and Dunton. The board has determined that the members of the audit committee are independent, as defined in the listing standards of the NYSE MKT, and satisfy the requirements of the NYSE MKT as to financial literacy and expertise. The board has determined that at least one member

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of the committee, Mr. deVeer, is the audit committee financial expert as defined by Item 407 of Regulation S-K. The responsibilities of the audit committee are set forth in a written charter adopted by the board and updated as of October 1, 2013, a copy of which is available on our website at [www.palatin.com](http://www.palatin.com).

### *Compensation Committee*

The compensation committee reviews and recommends to the board on an annual basis employment agreements and compensation for our officers, directors and some employees, and administers our 2011 Plan and the options still outstanding which were granted under previous stock option plans. The compensation committee is composed of Mr. deVeer and Drs. Horovitz, Taber (chair) and Dunton. The board has determined that the members of the compensation committee are independent, as defined in the listing standards of the NYSE MKT. Our chief executive officer aids the compensation committee by providing annual recommendations regarding the compensation of all executive officers, other than himself. Our chief financial officer supports the committee in its work by gathering, analyzing and presenting data on our compensation arrangements and compensation in the marketplace. The responsibilities of the compensation committee are set forth in a written charter adopted by the board effective October 1, 2013, a copy of which is available on our website at [www.palatin.com](http://www.palatin.com). The committee administers our 2011 Plan, under which it has delegated to an officer its authority to grant stock options to employees and to a single-member committee of the board its authority to grant restricted stock units to officers and to grant options and restricted stock units to our consultants, but in either instance not to grant options or restricted stock units to themselves, any member of the board or officer, or any person subject to Section 16 of the Exchange Act.

### **Nominating and Corporate Governance Committee**

The nominating and corporate governance committee assists the board in recommending nominees for directors, and in determining the composition of committees. It also reviews, assesses and makes recommendations to the board concerning policies and guidelines for corporate governance, including relationships of the board, the stockholders and management in determining our direction and performance. The responsibilities of the nominating and corporate governance committee are set forth in a written charter adopted by the board and updated as of October 1, 2013, a copy of which is available on our website at [www.palatin.com](http://www.palatin.com). The nominating and corporate governance committee is composed of Mr. Hull, Ms. Rossetti and Drs. Horovitz (chair) and Molinoff, each of whom meets the independence requirements established by the NYSE MKT.

## **Board Role In Risk Oversight**

Our board, as part of its overall responsibility to oversee the management of our business, considers risks generally when reviewing our strategic plan, financial results, business development activities, legal and regulatory matters. The board satisfies this responsibility through regular reports directly from our officers responsible for oversight of particular risks. The board's risk management oversight also includes full and open communications with management to review the adequacy and functionality of the risk management processes used by management. The board's role in risk oversight has no effect on the board's leadership structure. In addition, committees of the board assist in its risk oversight responsibility, including:

The audit committee assists the board in its oversight of the integrity of the financial reporting and our compliance with applicable legal and regulatory requirements. It also oversees our internal controls and compliance activities, and meets privately with representatives from our independent registered public accounting firm.

The compensation committee assists the board in its oversight of risk relating to compensation policies and practices. The compensation committee annually reviews our compensation policies, programs and procedures, including the

incentives they create and mitigating factors that may reduce the likelihood of excessive risk taking, to determine whether they present a significant risk to our company.

## **Board Leadership Structure**

Since 2000, the roles of chairman of the board and chief executive officer have been held by separate persons. John K.A. Prendergast, Ph.D., a non-employee director, has served as chairman of the board since June 2000. Carl Spana, Ph.D., has been our chief executive officer and president since June 2000. Generally, the chairman

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is responsible for advising the chief executive officer, assisting in long-term strategic planning, and presiding over meetings of the board, and the chief executive officer is responsible for leading our day-to-day performance. While we do not have a written policy with respect to separation of the roles of chairman of the board and chief executive officer, the board believes that the existing leadership structure, with the separation of these roles, provides several important advantages, including: enhancing the accountability of the chief executive officer to the board; strengthening the board's independence from management; assisting the board in reaching consensus on particular strategies and policies; and facilitating robust director, board, and executive officer evaluation processes.

## Code Of Corporate Conduct And Ethics

We have adopted a code of corporate conduct and ethics, updated as of October 1, 2013, that applies to all of our directors, officers and employees, including our chief executive officer and chief financial officer. You can view the code of corporate conduct and ethics at our website, [www.palatin.com](http://www.palatin.com). We will disclose any amendments to, or waivers from, provisions of the code of corporate conduct and ethics that apply to our directors, principal executive and financial officers in a current report on Form 8-K, unless the rules of the NYSE MKT permit website posting of any such amendments or waivers.

## Executive Officers

Executive officers are appointed by the board and serve at the discretion of the board. Each officer holds his position until his successor is appointed and qualified. The current executive officers hold office under employment agreements, which are each described below under Executive and Director Compensation Employment Agreements.

Name	Age	Position with Palatin
Carl Spana, Ph.D.	52	Chief Executive Officer, President and Director
Stephen T. Wills, MST, CPA	57	Chief Financial Officer, Chief Operating Officer, Executive Vice President, Secretary and Treasurer

Additional information about Dr. Spana is included above under the heading Executive Officers and Directors.

**Stephen T. Wills, MST, CPA**, has been vice president, secretary, treasurer and chief financial officer since 1997 and was executive vice president of operations from 2005 until June 2011, when he was appointed chief operating officer and executive vice president. From July 1997 to August 2000, Mr. Wills was also a vice president and the chief financial officer of Derma Sciences, Inc. (DSCI), or Derma, a publicly-held company which provides wound and skin care products, and currently serves as lead director of Derma. Mr. Wills was previously a director and chair of the audit committee of Miami International Securities Exchange, LLC, a privately-held fully-electronic options and equities exchange currently in development, and previously was a director of U.S. Helicopter Corp. (USHP), a publicly-held company. From 1991 to August 2000, he was the president and chief operating officer of Golomb, Wills & Company, P.C., a public accounting firm. Mr. Wills, a certified public accountant, received his B.S. in accounting from West Chester University, and an M.S. in taxation from Temple University.

TABLE OF CONTENTS**EXECUTIVE AND DIRECTOR COMPENSATION****Summary Compensation Table**

The following table summarizes the compensation earned by or paid to our principal executive officer and our principal financial officer, who are all of our named executive officers, for our fiscal years ended June 30, 2014 and 2013. We have no defined benefit or actuarial pension plan, and no deferred compensation plan.

Name and Principal Position	Fiscal Year	Salary (\$)	Stock Awards <sup>(1)</sup> (\$)	Option Awards <sup>(1)</sup> (\$)	Non-Equity Incentive Plan Compensation <sup>(2)</sup> (\$)	All Other Compensation <sup>(3)</sup> (\$)	Total Compensation <sup>(3)</sup> (\$)
Carl Spana, Ph.D., Chief Executive Officer and President	2014	450,000	178,500	143,083	170,000	22,500	964,083
	2013	436,771	217,400	245,971	250,000	12,938	1,163,080
Stephen T. Wills, MST, CPA, Chief Financial Officer, Chief Operating Officer and Executive Vice President	2014	410,000	153,000	122,643	140,000	17,376	843,019
	2013	394,167	203,200	222,742	225,000	13,000	1,058,109

Amounts in these columns represent the aggregate grant date fair value for stock awards and option awards (1) computed using the Black-Scholes model. For a description of the assumptions we used to calculate these amounts, see Note 9 to the consolidated financial statements included in this prospectus.

(2) Bonus amounts.  
(3) Consists of matching contributions to 401(k) plan.

**Employment Agreements**

Effective July 1, 2013, we entered into employment agreements with Dr. Spana and Mr. Wills which continue through June 30, 2016 unless terminated earlier. Under these agreements, which were approved by the compensation committee and the board and replace substantially similar agreements that expired on June 30, 2013, Dr. Spana is serving as chief executive officer and president at a base salary of \$450,000 per year and Mr. Wills is serving as chief financial officer and chief operating officer at a base salary of \$410,000 per year. Each agreement also provides for:

annual discretionary bonus compensation, in an amount to be decided by the compensation committee and approved by the board, based on achievement of yearly performance objectives; and participation in all benefit programs that we establish, to the extent the executive's position, tenure, salary, age, health and other qualifications make him eligible to participate.

Each agreement allows us or the executive to terminate the agreement upon written notice, and contains other provisions for termination by us for cause, or by the employee for good reason or due to a change in control (as these terms are defined in the employment agreements and set forth below). Early termination may, in some circumstances, result in severance pay at the salary then in effect, plus continuation of medical and dental benefits then in effect for a period of two years (Dr. Spana) or 18 months (Mr. Wills). In addition, the agreements provide that options and restricted stock units granted to these officers accelerate upon termination of employment except for voluntary



resignation by the officer or termination for cause. In the event of retirement, termination by the officer for good reason, or termination by us other than for cause, options may be exercised until the earlier of twenty-four months following termination or expiration of the option term. Arrangements with our named executive officers in connection with a termination following a change in control are described below. Each agreement includes non-competition, non-solicitation and confidentiality covenants.

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The compensation committee awarded performance-based cash bonuses to our named executive officers for fiscal 2014 and 2013, based on results of operations, including clinical trial operations and our financial condition. Bonuses for fiscal year 2013 were higher than for fiscal year 2014 for reasons including successful completion of Phase 2 trials of the company's lead product under development, bremelanotide for FSD, and completion of a private placement with gross proceeds of \$35,000,000.

## Stock Option and Restricted Stock Unit Grants

The compensation committee determined that additional equity grants were necessary in order to motivate and retain our executive officers. On June 25, 2014, we granted 175,000 restricted stock units to Dr. Spana and 150,000 restricted stock units to Mr. Wills, which vest as to 50% on each anniversary of the grant date. We also granted 175,000 stock options to Dr. Spana and 150,000 stock options to Mr. Wills, which vest as to 25% on each anniversary of the grant date. These options have an exercise price of \$1.02, the fair market value on the date of grant, and they expire on June 25, 2024.

On June 27, 2013, we granted 220,000 restricted stock units to Dr. Spana and 200,000 restricted stock units to Mr. Wills, which vest as to 50% on each anniversary of the grant date. We also granted 275,000 stock options to Dr. Spana and 250,000 to stock options Mr. Wills, which vest as to 25% on each anniversary of the grant date. These options have an exercise price of \$0.62, the fair market value on the date of grant, and they expire on June 27, 2023.

## Outstanding Equity Awards at 2014 Fiscal Year-End

The following table summarizes all of the outstanding equity-based awards granted to our named executive officers as of June 30, 2014, the end of our fiscal year.

Name	Option or Stock Award Grant Date	Option Awards <sup>(1)</sup>		Option Exercise Price (\$)	Option Expiration Date	Stock Awards <sup>(2)</sup>	
		Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)			Number of Shares or Units of Stock That Have Vested (#)	Market Value of Shares or Units of Stock That Have Vested (\$) <sup>(3)</sup>
Carl Spana	07/01/05	7,500		37.50	07/01/15		
	07/01/05	8,300		17.50	07/01/15		
	10/06/06	12,500		24.90	10/06/16		
	03/26/08	28,125		2.80	03/26/18		
	03/26/08	4,687		5.00	03/26/18		
	03/26/08	4,688		6.60	03/26/18		
	07/01/08	25,000		1.80	07/01/18		
	07/01/09	25,000		2.80	07/01/19		
	06/22/11	225,000	75,000	1.00	06/22/21		
	07/17/12	37,500	112,500	0.72	07/17/22		
	07/17/12					56,250	55,688

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	06/27/13	68,750	206,250	0.62	06/27/23		
	06/27/13					110,000	108,900
	06/25/14		175,000	1.02	06/25/24		
	06/25/14					175,000	173,250
Total Stock Awards						<b>341,250</b>	<b>\$337,838</b>
Stephen T. Wills	07/01/05	5,000		37.50	07/01/15		
	07/01/05	7,300		17.50	07/01/15		
	10/06/06	10,000		24.90	10/06/16		
	03/26/08	22,500		2.80	03/26/18		
	03/26/08	3,750		5.00	03/26/18		
	03/26/08	3,750		6.60	03/26/18		

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Name	Option or Stock Award Grant Date	Option Awards <sup>(1)</sup>			Stock Awards <sup>(2)</sup>		
		Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Yet Vested (#)	Market Value of Shares or Units of Stock That Have Not Yet Vested (\$) <sup>(3)</sup>
	07/01/08	20,000		1.80	07/01/18		
	07/01/09	20,000		2.80	07/01/19		
	06/22/11	187,500	62,500	1.00	06/22/21		
	07/17/12	33,750	101,250	0.72	07/17/22		
	07/17/12					55,000	54,450
	06/27/13	62,500	187,500	0.62	06/27/23		
	06/27/13					100,000	99,000
	06/25/14		150,000	1.02	06/25/24		
	06/25/14					150,000	148,500
Total Stock Awards						<b>305,000</b>	<b>\$301,950</b>

(1) Stock option vesting schedules: all options granted on or before July 1, 2009 have fully vested. Options granted after July 1, 2009 vest over four years with 1/4 of the shares vesting per year starting on the first anniversary of the grant date, provided that the named executive officer remains an employee. See Termination and Change-In-Control Arrangements below.

(2) Stock award vesting schedule: stock awards consist of restricted stock units granted on July 17, 2012, which had not vested as of June 30, 2014, but which vested on July 17, 2014; restricted stock units granted on June 27, 2013, which vested as to 50% on June 27, 2014 and will vest as to the remaining 50% on June 27, 2015; and restricted stock units granted on June 25, 2014, which will vest as to 50% on June 25, 2015 and 2016, provided that the named executive officer remains an employee. See Termination and Change-In-Control Arrangements below.

(3) Calculated by multiplying the number of restricted stock units by \$0.99, the closing market price of our common stock on June 30, 2014, the last trading day of our most recently completed fiscal year.

## Termination and Change-In-Control Arrangements

The employment agreements, stock option agreements and restricted stock unit agreements with Dr. Spana and Mr.

Wills contain the following provisions concerning severance compensation and the vesting of stock options and restricted stock units upon termination of employment or upon a change in control. The executive's entitlement to severance, payment of health benefits and accelerated vesting of options is contingent on the executive executing a general release of claims against us.

*Termination Without Severance Compensation.* Regardless of whether there has been a change in control, if we terminate employment for cause or the executive terminates employment without good reason (as those terms are defined in the employment agreement and set forth below), then the executive will receive only his accrued salary and vacation benefits through the date of termination. He may also elect to receive medical and dental benefits pursuant to COBRA for up to two years (Dr. Spana) or 18 months (Mr. Wills), but must remit the cost of coverage to us. Under the terms of our outstanding options and restricted stock units, all unvested options and restricted stock units would

terminate immediately, and vested options would be exercisable for three months after termination.

*Severance Compensation Without a Change in Control.* If we terminate or fail to extend the employment agreement without cause, or the executive terminates employment with good reason, then the executive will receive as severance pay his salary then in effect, paid in a lump sum, plus medical and dental benefits at our expense, for a period of two years (Dr. Spana) or 18 months (Mr. Wills) after the termination date. In addition, upon such event all unvested options would immediately vest and be exercisable for two years after the termination date or, if earlier, the expiration of the option term, and all unvested restricted stock units would accelerate and become fully vested.

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*Severance Compensation After a Change in Control.* If, within one year after a change in control, we terminate employment or the executive terminates employment with good reason, then the executive will receive as severance pay 200% (Dr. Spana) or 150% (Mr. Wills) of his salary then in effect, paid in a lump sum, plus medical and dental benefits at our expense, for a period of two years (Dr. Spana) or 18 months (Mr. Wills) after the termination date. We would also reimburse the executive for up to \$25,000 in fees and expenses during the six months following termination, for locating employment. We would also reimburse the executive for any excise tax he might incur on excess parachute payments (as defined in Section 280G(b) of the Internal Revenue Code). All unvested options would immediately vest and be exercisable for two years after the termination date or, if earlier, the expiration of the option term. All unvested restricted stock units would vest upon a change in control, without regard to whether the executive's employment is terminated.

*Option and Restricted Stock Unit Vesting Upon a Change in Control.* Options and restricted stock units granted under the 2011 Stock Incentive Plan vest upon a change in control. If any options granted under the 2005 Stock Plan are to be terminated in connection with a change in control, those options will vest in full immediately before the change in control.

*Definitions.* Under the employment agreements, a change in control, cause and good reason are defined as follows:

A change in control occurs when:

- (a) some person or entity acquires more than 50% of the voting power of our outstanding securities;
- (b) the individuals who, during any twelve month period, constitute our board of directors cease to constitute at least a majority of the board of directors;
- (c) we enter into a merger or consolidation; or
- (d) we sell substantially all our assets.

The term cause means:

- (a) the occurrence of (i) the executive's material breach of, or habitual neglect or failure to perform the material duties which he is required to perform under, the terms of his employment agreement; (ii) the executive's material failure to follow the reasonable directives or policies established by or at the direction of our board of directors; or (iii) the executive's engaging in conduct that is materially detrimental to our interests such that we sustain a material loss or injury as a result thereof, provided that the breach or failure of performance is not cured, to the extent cure is possible, within ten days of the delivery to the executive of written notice thereof;
- (b) the willful breach by the executive of his obligations to us with respect to confidentiality, invention and non-disclosure, non-competition or non-solicitation; or
- (c) the conviction of the executive of, or the entry of a pleading of guilty or nolo contendere by the executive to, any crime involving moral turpitude or any felony.

The term good reason means the occurrence of any of the following, with our failure to cure such circumstances within 30 days of the delivery to us of written notice by the executive of such circumstances:

- (a) any material adverse change in the executive's duties, authority or responsibilities, which causes the executive's position with us to become of significantly less responsibility, or assignment of duties and responsibilities inconsistent with the executive's position;
- (b) a material reduction in the executive's salary;

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- our failure to continue in effect any material compensation or benefit plan in which the executive participates, unless an equitable arrangement has been made with respect to such plan, or our failure to continue the executive's participation therein (or in a substitute or alternative plan) on a basis not materially less favorable, both in terms of the amount of benefits provided and the level of the executive's participation relative to other participants;
- (c) our failure to continue to provide the executive with benefits substantially similar to those enjoyed by the executive under any of our health and welfare insurance, retirement and other fringe-benefit plans, the taking of any action by us which would directly or indirectly materially reduce any of such benefits, or our failure to provide the executive with the number of paid vacation days to which he is entitled; or
- (d) the relocation of the executive to a location which is a material distance from Cranbury, New Jersey.
- (e)

**Director Compensation**

The following table sets forth the compensation we paid to all directors during fiscal 2014, except for Dr. Spana, whose compensation is set forth above in the Summary Compensation Table and related disclosure. Dr. Spana did not receive any separate compensation for his services as a director.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$) <sup>(2)</sup>	Option Awards (\$) <sup>(1)(2)</sup>	Total (\$)
John K.A. Prendergast, Ph.D.	87,500	30,600	21,673	139,773
Perry B. Molinoff, M.D.	47,000	15,300	10,837	73,137
Robert K. deVeer, Jr.	55,000	15,300	10,837	81,137
Zola P. Horovitz, Ph.D.	49,000	15,300	10,837	75,137
Robert I. Taber, Ph.D.	55,000	15,300	10,837	81,137
J. Stanley Hull	42,000	15,300	10,837	68,137
Alan W. Dunton, M.D.	50,000	15,300	10,837	76,137
Angela Rossetti	42,000	15,300	10,837	68,137

- (1) The aggregate number of shares underlying option awards and stock awards outstanding at June 30, 2014 for each director was:

	Option Awards	Stock Awards
Dr. Prendergast	278,350	30,000
Dr. Molinoff	166,833	15,000
Mr. deVeer	171,000	15,000
Dr. Horovitz	167,500	15,000
Dr. Taber	167,500	15,000
Mr. Hull	167,166	15,000
Dr. Dunton	92,500	15,000
Ms. Rossetti	45,000	15,000

- Amounts in these columns represent the aggregate grant date fair value for stock awards and option awards computed using the Black-Scholes model. For a description of the assumptions we used to calculate these amounts, see Note 9 to the consolidated financial statements included in this prospectus. Amounts in this column include options granted on June 25, 2014 for our current (2015) fiscal year.
- (2)

*Non-Employee Directors Option Grants.* Our non-employee directors receive an annual option grant at the board meeting closest to the beginning of each fiscal year, or such other date as may be determined by the board.



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On June 25, 2014, as the annual option grant for our current (2015) fiscal year, the chairman of the board, Dr. Prendergast, received 30,000 restricted stock units, which vest on June 25, 2015, and an option to purchase 30,000 shares of common stock, and each other serving non-employee director received 15,000 restricted stock units, which vest on June 25, 2015, and an option to purchase 15,000 shares of common stock. All of the options have an exercise price of \$1.02 per share, the closing price of our common stock on the date of grant, vest in twelve monthly installments beginning on July 31, 2014, expire ten years from the date of grant and provide for accelerated vesting in the event of involuntarily termination as a director following a change in control, with exercise permitted following accelerated vesting for up to the earlier of one year after termination or the expiration date of the option.

On June 27, 2013, as the annual option grant for our 2014 fiscal year, the chairman of the board, Dr. Prendergast, received an option to purchase 60,000 shares of common stock and each other serving non-employee director received an option to purchase 30,000 shares of common stock. All of these options have an exercise price of \$0.62 per share, the closing price of our common stock on the date of grant, vest in twelve monthly installments beginning on July 31, 2013 (subject to limitations on vesting which expired on September 1, 2013), expire ten years from the date of grant and provide for accelerated vesting in the event of involuntarily termination as a director following a change in control, with exercise permitted following accelerated vesting for up to the earlier of one year after termination or the expiration date of the option.

*Non-Employee Directors Cash Compensation.* Dr. Prendergast serves as chairman of the board and for our 2014 fiscal year received an annual retainer of \$87,500, payable quarterly. Other non-employee directors received an annual base retainer of \$40,000, payable on a quarterly basis. The chairperson of the audit committee received an additional annual retainer of \$10,000, the chairperson of the compensation committee received an additional annual retainer of \$7,000 and the chairperson of the corporate governance committee received an additional annual retainer of \$4,000. Members of the foregoing committees, other than the non-employee chairman, will receive an additional retainer of one-half the retainer payable to the committee chairperson. For the 2015 fiscal year, the chairperson of the audit committee will receive an additional annual retainer of \$12,500, and other members of the audit committee will receive an additional annual retainer of \$6,000; the chairperson of the compensation committee received an additional annual retainer of \$10,000; and the chairperson of the corporate governance committee will receive an additional annual retainer of \$6,000. Members of the compensation and corporate governance committees, other than the non-employee chairman, will receive an additional retainer of one-half the retainer payable to the committee chairperson.

*Non-Employee Directors Expenses.* Non-employee directors are reimbursed for expenses incurred in performing their duties as directors, including attending all meetings of the board and any committees on which they serve.

*Employee Directors.* Employee directors are not separately compensated for services as directors, but are reimbursed for expenses incurred in performing their duties as directors, including attending all meetings of the board and any committees on which they serve.

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## **CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

We have issued options to purchase shares of our common stock and restricted stock units to our named executive officers and members of our board of directors. For more information on these option and unit grants, please see the Executive and Director Compensation section of this prospectus.

As a condition of employment, we require all employees to disclose in writing actual or potential conflicts of interest, including related party transactions. Our code of corporate conduct and ethics, which applies to employees, officers and directors, requires that the audit committee review and approve related party transactions. Since July 1, 2011, there have been no transactions or proposed transactions in which we were or are to be a participant, in which any related person had or will have a direct or indirect material interest.

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The tables below show the beneficial stock ownership and voting power, as of September 29, 2014, of:

each director, each of the named executive officers, and all current directors and officers as a group; and all persons who, to our knowledge, beneficially own more than five percent of the outstanding shares of our common stock or Series A Preferred Stock.

Beneficial ownership here means direct or indirect voting or investment power over outstanding stock and stock which a person has the right to acquire now or within 60 days after September 29, 2014. See the footnotes for more detailed explanations of the holdings. Except as noted, to our knowledge, the persons named in the tables beneficially own and have sole voting and investment power over all shares listed.

The common stock has one vote per share and the Series A Preferred Stock has approximately 11.25 votes per share. Voting power is calculated on the basis of the aggregate of common stock and Series A Preferred Stock outstanding as of September 29, 2014, on which date 39,490,161 shares of common stock and 4,697 shares of Series A Preferred Stock, convertible into 52,829 shares of common stock, were outstanding.

The address for all members of our management is c/o Palatin Technologies, Inc., 4B Cedar Brook Drive, Cranbury, NJ 08512. Addresses of other beneficial owners are in the table.

**Management**

Class of Stock	Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class Beneficially Owned Before the Offering	Percent of Total Voting Power Beneficially Owned Before the Offering	Percent of Class Beneficially Owned After the Offering	Percent of Total Voting Power Beneficially Owned After the Offering
Common	Carl Spana, Ph.D.	964,713 (1)	2.4 %	1.1 %		
Common	Stephen T. Wills	878,137 (2)	2.2 %	1.1 %		
Common	John K.A. Prendergast, Ph.D.	252,617 (3)	*	*		
Common	Perry B. Molinoff, M.D.	162,833 (4)	*	*		
Common	Robert K. deVeer, Jr.	176,060 (5)	*	*		
Common	Zola P. Horovitz, Ph.D.	161,000 (6)	*	*		
Common	Robert I. Taber, Ph.D.	156,000 (7)	*	*		
Common	J. Stanley Hull	154,166 (8)	*	*		
Common	Alan W. Dunton, M.D.	85,020 (9)	*	*		
Common	Angela Rossetti	35,000 (10)	*	*		
	All current directors and executive officers as a	3,025,546 <sup>(11)</sup>	7.3 %	2.3 %		

group (ten persons)

\*

Less than one percent.

- (1) Includes 484,550 shares which Dr. Spana has the right to acquire under options, and 50,000 shares which he has the right to acquire under warrants.
- (2) Includes 409,800 shares which Mr. Wills has the right to acquire under options, and 50,000 shares which he has the right to acquire under warrants.
  - (3) Includes 250,850 shares which Dr. Prendergast has the right to acquire under options.
  - (4) Includes 151,833 shares which Dr. Molinoff has the right to acquire under options.
  - (5) Includes 154,000 shares which Mr. deVeer has the right to acquire under options.
  - (6) Includes 150,500 shares which Dr. Horovitz has the right to acquire under options.
  - (7) Includes 150,500 shares which Dr. Taber has the right to acquire under options.
  - (8) Includes 152,166 shares which Mr. Hull has the right to acquire under options.
  - (9) Includes 77,500 shares which Dr. Dunton has the right to acquire under options.

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(10) Shares which Ms. Rossetti has the right to acquire under options.

(11) Includes 2,116,699 shares which directors and officers have the right to acquire under options and warrants.

**More Than 5% Beneficial Owners**

Class of Stock	Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership <sup>(1)</sup>	Percent of Class Beneficially Owned Before the Offering	Percent of Total Voting Power Beneficially Owned Before the Offering	Percent of Class Beneficially Owned After the Offering	Percent of Total Voting Power Beneficially Owned After the Offering
Common	Mark N. Lampert BVF Inc. BVF Partners L.P. 900 North Michigan Avenue Suite 1100 Chicago, Illinois 60611	4,150,655 <sup>(2)</sup>	9.7 %	1.9 %		
Common	QVT Financial LP 1177 Avenue of the Americas, 9 <sup>th</sup> Floor New York, New York 10036	3,950,858 <sup>(3)</sup>	9.9 %	9.8 %		
Common	James E. Flynn 780 Third Avenue, 37 <sup>th</sup> Floor New York, NY 10017	4,160,945 <sup>(4)</sup>	9.9 %	5.1 %		
Common	Great Point Partners LLC Jeffrey R. Jay, M.D. David Kroin 165 Mason Street, 3 <sup>rd</sup> Floor Greenwich, CT 06830	2,337,000 <sup>(5)</sup>	5.6 %	*		
Series A Preferred	Tokenhouse PTE LTD 9 11 Reitergasse Zurich 8027, Switzerland	667	14.2 %	*		
Series A Preferred	Steven N. Ostrovsky 43 Nikki Ct. Morganville, NJ 07751	500	10.6 %	*		
Series A Preferred	Thomas L. Cassidy IRA Rollover 38 Canaan Close New Canaan, CT 06840	500	10.6 %	*		

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Series A Preferred	Jonathan E. Rothschild 300 Mercer St., #28F New York, NY 10003	500	10.6	%	*
Series A Preferred	Arthur J. Nagle 19 Garden Avenue Bronxville, NY 10708	250	5.3	%	*
Series A Preferred	Thomas P. and Mary E. Heiser, JTWROS	250	5.3	%	*
Series A Preferred	10 Ridge Road Hopkinton, MA 01748 Carl F. Schwartz	250	5.3	%	*
Series A Preferred	31 West 87 <sup>th</sup> St. New York, NY 10016 Michael J. Wrubel	250	5.3	%	*
Series A Preferred	3650 N. 36 Avenue, #39 Hollywood, FL 33021 Myron M. Teitelbaum, M.D.	250	5.3	%	*
Series A Preferred	175 Burton Lane Lawrence, NY 11559 Laura Gold Galleries Ltd. Profit Sharing Trust Park South Gallery	250	5.3	%	*
Series A Preferred	at Carnegie Hall 154 West 57 <sup>th</sup> Street, Suite 114 New York, NY 10019-3321	250	5.3	%	*

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Class of Stock	Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership <sup>(1)</sup>	Percent of Class Beneficially Owned Before the Offering	Percent of Total Voting Power Beneficially Owned Before the Offering	Percent of Class Beneficially Owned After the Offering	Percent of Total Voting Power Beneficially Owned After the Offering
Series A Preferred	Laura Gold 180 W. 58 <sup>th</sup> Street New York, NY 10019	250	5.3 %	*		

\*

Less than one percent.

(1) Unless otherwise indicated by footnote, all share amounts represent outstanding shares of the class indicated, and all beneficial owners listed have, to our knowledge, sole voting and dispositive power over the shares listed.

According to a joint Schedule 13G/A filed on September 15, 2014, Mr. Lampert, BVF Partners L.P. and BVF, Inc. share voting and dispositive power with respect to all the shares listed, and the other filers have beneficial

(2) ownership as follows, as to which Mr. Lampert, BVF Partners L.P. and BVF, Inc. disclaim beneficial ownership.

The shares beneficially owned by the other filers, as updated on the joint Schedule 13G/A filed on September 15, 2014, are:

- (i) BVF Investments, L.L.C.: 1,977,093 shares, including 1,566,487 shares issuable on exercise of warrants;
- (ii) Biotechnology Value Fund, L.P.: 941,601 shares, including 784,000 shares issuable on exercise of warrants;
- (iii) Biotechnology Value Fund II, L.P.: 623,725 shares, including 542,000 shares issuable on exercise of warrants;
- (iv) MSI BVF SPV, LLC: 369,145 shares, including 312,513 shares issuable on exercise of warrants; and
- (v) Investment 10, L.L.C.: 239,091 shares, including 195,000 shares issuable on exercise of warrants.

Includes 57,976 shares issuable on exercise of warrants. According to a joint Schedule 13G filed on July 10, 2012, QVT Financial LP, or QVT Financial, is the investment manager for QVT Fund IV LP, or Fund IV, which beneficially owns 501,360 shares of common stock, for QVT Fund V LP, or Fund V, which beneficially owns

(3) 2,956,894 shares of common stock, and for Quintessence Fund L.P., or Quintessence, which beneficially owns 434,628 shares of common stock. QVT Financial has the power to direct the vote and disposition of the common stock held by Fund IV, Fund V and Quintessence. Accordingly, QVT Financial may be deemed to be the beneficial owner of an aggregate amount of 3,892,882 shares of common stock, consisting of the shares beneficially owned by Fund IV, Fund V and Quintessence.

QVT Financial GP LLC, as General Partner of QVT Financial, may be deemed to beneficially own the same number of shares of common stock reported by QVT Financial. QVT Associates GP LLC, as General Partner of Fund IV, Fund V and Quintessence, may be deemed to beneficially own the aggregate number of shares of common stock beneficially owned by Fund IV, Fund V and Quintessence, and accordingly, QVT Associates GP LLC may be deemed to be the beneficial owner of an aggregate amount of 3,892,882 shares of common stock.

Exercise of the warrants is restricted if, as a result of an exercise, the beneficial ownership of the holder and its affiliates and any other party or person that could be deemed to be a group would exceed 9.99% of the outstanding common stock. Beneficial ownership as listed in the table above excludes warrants which are not exercisable because of that restriction.

(4) Includes 2,160,945 shares issuable on exercise of warrants. According to a joint Schedule 13G/A filed on February 14, 2014, Mr. Flynn and the other filers had beneficial ownership and shared voting and dispositive power as

follows:

- James E. Flynn: 2,000,000 shares outstanding and 3,250,000 shares issuable on exercise of warrants held by Deerfield Special Situations Fund, L.P. and Deerfield Special Situations Fund International Limited. Mr. Flynn
- (i) shares voting and dispositive power over the shares owned by Deerfield Special Situations Fund, L.P. and Deerfield Special Situations Fund International Limited.
  - Deerfield Mgmt, L.P.: 2,000,000 shares outstanding and 3,250,000 shares issuable on exercise of warrants held by
  - (ii) Deerfield Special Situations Fund, L.P. and Deerfield Special Situations International Master Fund, L.P., of which Deerfield Mgmt, L.P. is the general partner.

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(iii) Deerfield Management Company, L.P.: 2,000,000 shares outstanding and 3,250,000 shares issuable on exercise of warrants held by Deerfield Special Situations Fund, L.P. and Deerfield Special Situations International Master Fund, L.P., of which Deerfield Management Company, L.P. is the investment advisor.

(iv) Deerfield Special Situations Fund L.P.: 1,098,000 shares outstanding and 1,287,000 shares issuable on exercise of warrants.

(v) Deerfield Special Situations International Master Fund, L.P.: 902,000 shares outstanding and 1,963,000 shares issuable on exercise of warrants.

Exercise of the warrants is restricted if, as a result of exercise, the beneficial ownership of the holder or any group including the holder would exceed 9.99% of the outstanding common stock. Beneficial ownership as listed in the table above excludes warrants which are not exercisable because of that restriction.

Shares issuable on exercise of warrants. Dr. Jay and Mr. Kroin are managing members of Great Point Partners, LLC. According to a joint Schedule 13G/A filed on February 14, 2014, each of the owners listed had shared voting (5) and dispositive power with respect to all the shares listed. Great Point Partners, LLC is the investment manager for the following entities or persons, which have shared voting and dispositive power over the number of shares indicated:

- (i) Biomedical Value Fund, LP: 762,692 shares issuable on exercise of warrants;
- (ii) Biomedical Offshore Value Fund, Ltd.: 439,819 shares issuable on exercise of warrants;
- (iii) Biomedical Institutional Value Fund, LP: 282,815 shares issuable on exercise of warrants;
- (iv) Lyrical Multi-Manager Fund, LP: 265,834 shares issuable on exercise of warrants;
- (v) Lyrical Multi-Manager Fund Offshore Fund, Ltd.: 115,513 shares issuable on exercise of warrants;
- (vi) Class D Series of GEF-PS, LP: 381,347 shares issuable on exercise of warrants;
- (vii) David J. Morrison: 12,712 shares issuable on exercise of warrants; and
- (viii) WS Investments III, LLC: 76,269 shares issuable on exercise of warrants.

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## DESCRIPTION OF SECURITIES

The following description of our capital stock is intended as a summary only and is qualified in its entirety by reference to our amended and restated certificate of incorporation and bylaws, which are filed as exhibits to the registration statement of which this prospectus forms a part.

### General

Our authorized capital stock as of September 29, 2014 consists of:

300,000,000 shares of common stock, par value \$0.01 per share; and  
10,000,000 shares of preferred stock, par value \$0.01 per share, of which 9,736,000 shares are undesignated.

### Common Stock

*Outstanding Shares.* As of September 29, 2014 we had outstanding:

39,490,161 shares of our common stock held of record by 94 stockholders;  
options to purchase 4,229,913 shares of our common stock under our stock plans, at exercise prices ranging from \$0.60 to \$37.50 per share, with options for 2,621,688 shares vested and exercisable, at a weighted average exercise price of \$2.01;

91,251,531 shares issuable on the exercise of warrants at exercise prices ranging from \$0.01 to \$1.50 per share, which includes warrants issued in our 2012 private placement for 67,476,531 shares issuable at an exercise price of \$0.01 per share;

845,900 shares of common stock issuable under restricted stock units which vest on dates between June 25, 2015 and June 25, 2018, subject to the fulfillment of service conditions; and

4,697 shares of Series A Convertible Preferred Stock, convertible into 52,829 shares of common stock.

We currently have 7,000,000 shares of common stock reserved for issuance under our equity incentive plans, of which 1,935,116 shares currently remain available for issuance.

*Voting.* Holders of our common stock are entitled to one vote for each share held of record for the election of directors and on all other matters that require stockholder approval and are properly submitted to a vote of the stockholders. Holders of shares of common stock do not have any cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

*Dividends.* Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. As described below under Series A Convertible Preferred Stock, our outstanding Series A Preferred Stock provides that we may not pay a dividend or make any distribution to holders of any class of stock unless we first pay a special dividend or distribution of \$100 per share to the holders of the Series A Preferred Stock.

*Liquidation.* Subject to any preferential rights of any outstanding preferred stock, in the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in the assets remaining after payment of liabilities and the liquidation preferences of any outstanding preferred stock.

*Rights and preferences.* Our common stock does not carry any redemption rights or any preemptive or preferential rights enabling a holder to subscribe for, or receive shares of, any class of our common stock or any other securities convertible into shares of any class of our common stock. See [Description of Securities](#) [Warrants](#) for the contractual rights of the QVT funds.

*Fully paid and nonassessable.* All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

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## Preferred Stock

We have the authority to issue 10,000,000 shares of preferred stock. As of September 29, 2014, 264,000 shares of our preferred stock were designated as a single class, Series A Convertible Preferred Stock, of which 4,697 shares were outstanding (see Series A Convertible Preferred Stock below). The description of preferred stock provisions set forth below is not complete and is subject to and qualified in its entirety by reference to our amended and restated certificate of incorporation and the certificate of designations relating to the Series A Convertible Preferred Stock.

The board of directors has the right, without the consent of holders of common stock, to designate and issue one or more series of preferred stock, which may be convertible into common stock at a ratio determined by the board. A series of preferred stock may bear rights superior to common stock as to voting, dividends, redemption, distributions in liquidation, dissolution, or winding up, and other relative rights and preferences. The board may set the following terms of any series preferred stock:

the number of shares constituting the series and the distinctive designation of the series;  
dividend rates, whether dividends are cumulative, and, if so, from what date and the relative rights of priority of payment of dividends;

voting rights and the terms of the voting rights;  
conversion privileges and the terms and conditions of conversion, including provision for adjustment of the conversion rate;  
redemption rights and the terms and conditions of redemption, including the date or dates upon or after which shares may be redeemable, and the amount per share payable in case of redemption, which may vary under different conditions and at different redemption dates;

sinking fund provisions for the redemption or purchase of shares;  
rights in the event of voluntary or involuntary liquidation, dissolution or winding up of the corporation, and the relative rights of priority of payment; and

any other relative powers, preferences, rights, privileges, qualifications, limitations and restrictions of the series.

*Dividends.* Dividends on outstanding shares of preferred stock, if and when issued, will be paid or declared and set apart for payment before any dividends may be paid or declared and set apart for payment on the common stock with respect to the same dividend period.

*Liquidation.* If upon any voluntary or involuntary liquidation, dissolution or winding up of the corporation, the assets available for distribution to holders of preferred stock, if and when issued, are insufficient to pay the full preferential amount to which the holders are entitled, then the available assets will be distributed ratably among the shares of all series of preferred stock in accordance with the respective preferential amounts (including unpaid cumulative dividends, if any) payable with respect to each series.

*Preemptive rights.* Holders of preferred stock, if and when issued, will not be entitled to preemptive rights to purchase or subscribe for any shares of any class of capital stock of the corporation.

*Fully paid and nonassessable.* The preferred stock will, if and when issued, be fully paid and nonassessable.

*Subordinate.* The rights of the holders of preferred stock, if and when issued, will be subordinate to those of our general creditors.

## **Series A Convertible Preferred Stock**

The board of directors established a series of 264,000 shares of preferred stock, designated Series A Convertible Preferred Stock, par value \$0.01 per share, or Series A. We issued 137,780 shares of Series A in 1997, of which 4,697 shares remain outstanding as of September 29, 2014, the rest having been converted into common stock. The Series A has the following rights and preferences.

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*Optional conversion.* Each share of Series A is convertible at any time, at the option of the holder, into the number of shares of common stock equal to \$100 divided by the conversion price, as defined in the Series A certificate of designations. The current conversion price is \$8.89, so each share of Series A is currently convertible into approximately 11.25 shares of common stock.

*Mandatory conversion.* We may, at our option, cause the conversion of the Series A, in whole or in part, on a pro rata basis, into common stock, if the closing bid price of the common stock has exceeded 200% of the conversion price for at least 20 trading days in any 30 consecutive trading day period, ending three days prior to the date of mandatory conversion.

*Price protection provisions.* The conversion price decreases if we sell common stock (or equivalents) for a price per share less than the conversion price or less than the market price of the common stock. The conversion price is also subject to adjustment upon the occurrence of a merger, reorganization, consolidation, reclassification, stock dividend or stock split which results in an increase or decrease in the number of shares of common stock outstanding.

*Dividend and distribution preference.* We may not pay a dividend or make any distribution to holders of any other capital stock unless and until we first pay a special dividend or distribution of \$100 per share to the holders of Series A.

*Liquidation preference.* Upon (i) liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, (ii) sale or other disposition of all or substantially all of the assets of the Company, or (iii) any consolidation, merger, combination, reorganization or other transaction in which Palatin is not the surviving entity or in which the shares of common stock constituting in excess of 50% of the voting power of the Company are exchanged for or changed into other stock or securities, cash and/or any other property, after payment or provision for payment of the debts and other liabilities of the Company, the holders of Series A will be entitled to receive, pro rata and in preference to the holders of any other capital stock, an amount per share equal to \$100 plus accrued but unpaid dividends, if any.

*Voting rights.* Each holder of Series A has the number of votes equal to the number of shares of common stock issuable upon conversion of the holder's Series A at the record date for determination of the stockholders entitled to vote or, if no record date is established, at the date a vote is taken. Except as provided above or as required by applicable law, the holders of the Series A are entitled to vote together with the holders of the common stock and not as a separate class.

## **Warrants**

As of September 29, 2014, we had outstanding warrants to purchase an aggregate of 91,251,531 shares of common stock.

On July 3, 2012, we closed on a private placement offering (our 2012 private placement) in which we sold, for aggregate proceeds of \$35.0 million, 3,873,000 shares of our common stock, Series A 2012 warrants to purchase up to 31,988,151 shares of common stock, and Series B 2012 warrants to purchase up to 35,488,380 shares of common stock to funds under the management of QVT Financial LP (collectively, the QVT funds). These warrants are exercisable at an exercise price of \$0.01 per share, and expire ten years from the date of issuance. The holders may exercise the warrants on a cashless basis. The warrants are subject to a blocker provision prohibiting exercise of the warrants if the holder and its affiliates would beneficially own in excess of 9.99% of the total number of shares of our common stock following such exercise (as may be adjusted to the extent set forth in the warrant). Pursuant to the

registration rights agreement between the Company and QVT funds, we have filed resale registration statements to register the common stock issued and issuable upon the exercise of the warrants held by the QVT funds.

For six years after our 2012 private placement, unless the purchasers own less than 20% of our outstanding common stock calculated as if the warrants were exercised, the purchasers have the right of first negotiation on any subsequent equity or debt financing. If we do not agree to terms of a financing with them, and negotiate with a third party on a financing, we must offer to sell to the purchasers at least 55% of the financing, and the purchasers may elect to purchase all or a portion of the financing. We expect that the purchasers will waive their right of first negotiation and right of participation, along with other rights granted to them in the transaction documents for the 2012 private placement, prior to the closing of this offering.

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Under the purchase agreement and form of warrants for our 2012 private placement, if we permit, make or allow a takeover, change of control or other fundamental transaction, including any transfer of all or substantially all of our properties or assets, then so long as any warrants remain outstanding we are required, as elected by the warrant holders, to pay such holders a warrant early termination price tied to the greater of the then market price of our common stock or the amount per share paid to any other person.

In addition, under the purchase agreement and form of warrants for our 2012 private placement, so long as any warrants remain outstanding we are required to (i) not permit, (ii) take necessary action to prevent both the occurrence or consummation of, and (iii) not be a party to any fundamental transaction, change of control or similar event unless contractually-specified rights are provided with respect to payment of a warrant early termination price tied to the greater of the then market price of our common stock or the amount per share paid to any other person. We are also required, subject to the exercise by our board of its fiduciary duties, to take all reasonable efforts to adopt a poison pill or any other anti-takeover provision or method necessary to prevent the fundamental transaction, change of control or similar event.

The application of these provisions could have the effect of delaying or preventing a change of control or other fundamental transaction.

## **Anti-Takeover Effects of Provisions of Delaware Law and Our Charter Documents**

*Amended and Restated Certificate of Incorporation.* Our amended and restated certificate of incorporation authorizes the issuance of up to 10,000,000 shares of preferred stock, par value \$.01 per share, of which 264,000 shares are currently designated as Series A Convertible Preferred Stock. The board of directors has the authority, without further approval of the stockholders, to issue and determine the rights and preferences of other series of preferred stock, except as limited by the certificate of designation for the Series A. The board could issue one or more series of preferred stock with voting, conversion, dividend, liquidation, or other rights which would adversely affect the voting power and ownership interest of holders of common stock. This authority may have the effect of deterring hostile takeovers, delaying or preventing a change in control, and discouraging bids for our common stock at a premium over the market price.

*Section 203 of the Delaware General Corporation Law.* We are subject to Section 203 of the Delaware General Corporation Law, which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the time that such stockholder became an interested stockholder, unless:

prior to such time, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned (a) by persons who are directors and also officers and (b) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two thirds of the outstanding voting stock which is not owned by the interested stockholder.





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In general, Section 203 defines *business combination* to include the following:

any merger or consolidation involving the corporation and the interested stockholder;  
any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;  
subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;  
any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or  
the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines *interested stockholder* as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

*Indemnification and Limitation of Liability.* Our amended and restated certificate of incorporation and bylaws require us to indemnify our directors, officers, employees and agents against the costs (including fines, judgments and attorney fees) from involvement in legal proceedings arising from their position or service, provided that the person seeking indemnification acted:

in good faith;  
in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation; and  
with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.  
The amended and restated certificate of incorporation and bylaws allow us to buy indemnification insurance for this purpose.

Our certificate of incorporation provides that, to the fullest extent permissible under Delaware law, no director shall be personally liable to the corporation or its stockholders for monetary damages for breach of a fiduciary duty as a director. However, this provision does not eliminate the duty of care, and in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief that will remain available under Delaware law. In addition, each director will continue to be subject to liability for (a) breach of the director's duty of loyalty to us or our stockholders, (b) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (c) violating Section 174 of the Delaware General Corporation Law, or (d) any transaction from which the director derived an improper personal benefit. The provision also does not affect a director's responsibilities under any other law, such as the federal securities laws or state or federal environmental laws.

## **Market Information**

Our common stock is quoted on the NYSE MKT under the symbol *PTN*. On September 26, 2014, the closing price of our common stock was \$0.87.

## **Transfer Agent and Registrar**

The transfer agent for our common stock is American Stock Transfer & Trust Company, located at 6201 15<sup>th</sup> Avenue, Brooklyn, NY 11219.



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## **MATERIAL U.S. TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK**

The following is a summary of material U.S. federal income tax considerations of the ownership and disposition of our common stock to non-U.S. holders. It is not intended to be a complete analysis of all the U.S. federal income tax considerations that may be relevant to non-U.S. holders. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Code. U.S. Treasury Regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly with retroactive effect, which may result in U.S. federal income tax consequences different from those set forth below. We have not sought any ruling from the Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following summary. There can be no assurance that the IRS will agree with such statements and conclusions or that any contrary position taken by the IRS would not be sustained by a court.

This summary also does not address the tax considerations arising under the laws of any foreign, state or local jurisdiction or any alternative minimum tax considerations. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

banks, insurance companies, real estate investment trusts, regulated investment companies or other financial institutions;

tax-exempt organizations, retirement plans, individual retirement accounts and tax-deferred accounts;  
dealers in securities or currencies;

traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;  
persons that own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);

controlled foreign corporations or passive foreign investment companies;  
certain former citizens or long-term residents of the United States;

persons who hold our common stock as a position in a hedging transaction, straddle, conversion transaction or other risk reduction transaction;

persons deemed to sell our common stock under the constructive sale provisions of the Code; or  
persons who hold our common stock other than as a capital asset (generally, an asset held for investment purposes).

In addition, if a partnership or other entity classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our common stock, and partners in such partnerships, should consult their tax advisors.

**YOU ARE URGED TO CONSULT YOUR TAX ADVISOR WITH  
RESPECT TO THE APPLICATION OF THE UNITED STATES  
FEDERAL INCOME TAX LAWS TO YOUR PARTICULAR  
SITUATION, AS WELL AS ANY TAX CONSEQUENCES OF THE  
PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON  
STOCK ARISING UNDER THE UNITED STATES FEDERAL**

**ESTATE OR GIFT TAX RULES OR UNDER THE LAWS OF ANY  
STATE, LOCAL, FOREIGN OR OTHER TAXING JURISDICTION  
OR UNDER ANY APPLICABLE TAX TREATY.**

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## Distributions on Shares of Our Common Stock

A non-U.S. holder is any holder other than:

an individual U.S. citizen or resident (as determined for U.S. federal income tax purposes);  
a corporation (or other entity that is classified as a corporation for U.S. federal income tax purposes)  
organized under the laws of the U.S. or any of its political subdivisions;

an estate the income of which is subject to U.S. federal income taxation regardless of its source; or  
a trust if (i) a court within the U.S. is able to exercise primary jurisdiction over the administration of the trust and one or more United States persons (as defined for U.S. federal income tax purposes) have the authority to control all substantial decisions of the trust or (ii) the trust has a valid election in effect under current U.S. Treasury Regulations to be treated as a United States person.

Distributions that are treated as dividends generally will be subject to United States federal withholding tax at a rate of 30% of the gross amount of the dividends, or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish to us or our paying agent a valid IRS Form W-8BEN (for individuals) or IRS Form W-8BEN-E (for entities) (or applicable successor form) certifying such non-U.S. holder's qualification for the reduced rate. This certification must be provided to us or our paying agent prior to the payment of dividends and must be updated periodically. Non-U.S. holders that do not timely provide us or our paying agent with the required certification, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If a non-U.S. holder holds shares of our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on the shares of our common stock are effectively connected with such non-U.S. holder's United States trade or business (and if required by an applicable income tax treaty, attributable to a permanent establishment maintained by the non-U.S. holder in the United States), the non-U.S. holder will be exempt from United States federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish to us or our paying agent a properly executed IRS Form W-8ECI (or applicable successor form).

Any dividends paid on shares of our common stock that are effectively connected with a non-U.S. holder's United States trade or business (and if required by an applicable income tax treaty, attributable to a permanent establishment maintained by the non-U.S. holder in the United States) generally will be subject to United States federal income tax on a net income basis at the regular graduated United States federal income tax rates in much the same manner as if such non-U.S. holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Distributions in excess of our current and accumulated earnings and profits, as determined under United States federal income tax principles, will constitute a return of capital and will first be applied against and reduce a non-U.S. holder's tax basis in the shares of our common stock, but not below zero. Distributions in excess of our current and accumulated earnings and profits and in excess of a non-U.S. holder's tax basis in its shares of our common stock may be subject to United States federal income tax as gain realized on the sale or other disposition of the shares of our common stock as described under [Sale or Other Taxable Dispositions of Shares of Our Common Stock](#) below.

## **Sale or Other Taxable Dispositions of Shares of Our Common Stock**

Subject to the discussion of backup withholding and withholding tax relating to foreign accounts below, a non-U.S. holder generally will not be subject to United States federal income tax on any gain realized upon the sale or other disposition of the common stock, unless:

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the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States, and if required by an applicable income tax treaty, attributable to a permanent establishment maintained by the non-U.S. holder in the United States;

the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or

our common stock constitutes a United States real property interest, or USRPI, within the meaning of the Foreign Investment in Real Property Tax Act, or FIRPTA, by reason of our status as a United States real property holding corporation, or USRPHC, for United States federal income tax purposes.

Gain described in the first bullet point above will be subject to United States federal income tax on a net income basis at the regular graduated United States federal income tax rates in much the same manner as if such non-U.S. holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain described in the second bullet point above will be subject to United States federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but generally may be offset by United States source capital losses.

With respect to the third bullet point above, we believe we will not be a USRPHC for United States federal income tax purposes. Because the determination of whether we are a USRPHC depends on the fair market value of our United States real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests, it is possible we could become a USRPHC in the future. As a USRPHC, if a class of our stock is regularly traded on an established securities market, such stock will be treated as a USRPI only with respect to a non-U.S. holder that actually or constructively holds more than five percent of such class of stock at any time during the shorter of the five-year period preceding the date of disposition or the holder's holding period for such stock. We anticipate that our common stock will be regularly traded on an established securities market following this offering. However, no assurance can be given in this regard and no assurance can be given that our common stock will remain regularly traded in the future. Non-U.S. holders should consult their tax advisors concerning the consequences of disposing of shares of our common stock.

If gain on the sale or other taxable disposition of shares of our common stock were subject to taxation under FIRPTA as a sale of a USRPI, the non-U.S. holder would generally be subject to regular United States federal income tax with respect to such gain in the same manner as a taxable U.S. holder. In addition, if the sale or other taxable disposition of shares of our common stock is subject to tax under FIRPTA, the purchaser of the stock would be required to withhold and remit to the IRS 10% of the purchase price unless an exception applies.

A non-U.S. holder will be required to file a United States federal income tax return for any taxable year in which it realizes a gain from the disposition of our common stock that is subject to United States federal income tax.

## **Backup Withholding Tax and Information Reporting**

We must report annually to each non-U.S. holder of shares of our common stock and to the IRS the amount of payments on the shares of our common stock paid to such non-U.S. holder and the amount of any tax withheld with respect to those payments. These information reporting requirements apply even if no withholding was required because the payments were effectively connected with the non-U.S. holder's conduct of a United States trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be



made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, however, generally will not apply to distribution payments to a non-U.S. holder of shares of our common stock provided the non-U.S. holder furnishes to us or our paying agent the required certification as to its

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non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-8ECI (or other applicable successor form), or certain other requirements are met. Notwithstanding the foregoing, backup withholding may apply if either we or our paying agent has actual knowledge, or reason to know, that the holder is a U.S. person that is not an exempt recipient.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's United States federal income tax liability, provided the required information is timely furnished to the IRS.

## **Additional Withholding Tax Relating to Foreign Accounts**

Withholding taxes may apply to certain types of payments made to foreign financial institutions (as specially defined in the IRC) and certain other non-United States entities. Specifically, and subject to any intergovernmental agreement that the U.S. has entered, or may enter, into with the country that a non-U.S. holder is a resident of, a 30% withholding tax may be imposed on dividends on, and gross proceeds from the sale or other disposition of, shares of our common stock paid to a foreign financial institution or to a non-financial foreign entity, unless (1) the foreign financial institution undertakes certain diligence and reporting, (2) the non-financial foreign entity either certifies it does not have any substantial United States owners or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain U.S. persons or U.S.-owned foreign entities, annually report certain information about such accounts, and withhold 30% on payments to non-compliant foreign financial institutions and certain other account holders. Under certain circumstances, a payee may not be eligible for a refund or credit of such withholding taxes. The U.S. Department of the Treasury has issued administrative guidance providing that these withholding provisions will generally only apply to payments of dividends made on or after July 1, 2014, and to payments of gross proceeds from a sale or other disposition of stock on or after January 1, 2017.

The preceding discussion of certain foreign income tax consequences is for general information only and is not tax advice. Accordingly, each investor should consult its own tax advisor as to the particular tax consequences to it of purchasing, holding and disposing of shares of our common stock, including the applicability and effect of any foreign tax laws, and of any pending or subsequent changes in applicable laws.

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## UNDERWRITING

We are offering the shares of common stock described in this prospectus through Piper Jaffray & Co. as the sole book-running manager. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and the underwriters have severally agreed to purchase from us, the number of shares of common stock set forth opposite their respective names in the table below.

Underwriter	Number of Shares
Piper Jaffray & Co.	
Total	

Each underwriter is committed to purchase all the shares of common stock offered by us if it purchases any shares, other than those shares covered by the over-allotment option described below.

The underwriters have advised us that they propose to offer the common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$     per share. After the offering, these figures may be changed by the underwriters.

We have granted the underwriters an option to buy up to     additional shares of our common stock from us, at the same price to the public, to cover over-allotments. The underwriters may exercise this option at any time and from time to time during the 30-day period after the date of this prospectus.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters in connection with this offering assuming both no exercise and full exercise of the underwriters' over-allotment option.