SOPHIRIS BIO INC.
Form 424B7
June 24, 2014
Table Of Contents

Filed pursuant to Rule 424(b)(7)

Registration No. 333-196331

PROSPECTUS

3,409,629 Shares

Sophiris Bio Inc.

Common Shares

This prospectus relates to the sale of up to 3,409,629 of our common shares, no par value, by Aspire Capital Fund, LLC. Aspire Capital is also referred to in this prospectus as the selling shareholder. The prices at which the selling shareholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the selling shareholder. However, we may receive proceeds of up to $15.0 million from the sale of our common shares to the selling shareholder, pursuant to a common stock purchase agreement entered into with the selling shareholder on May 16, 2014, including proceeds that we have already received thereunder.

The selling shareholder is an “underwriter” within the meaning of the Securities Act of 1933, as amended. We will pay the expenses of registering these shares, but all selling and other expenses incurred by the selling shareholder will be paid by the selling shareholder.

Our common shares trade on the NASDAQ Global Market, or NASDAQ, under the ticker symbol “SPHS”. On June 16, 2014, the last reported sale price per common share was $2.40 per share.

You should read this prospectus, together with additional information described under the headings "Incorporation of Certain Documents by Reference" and "Where You Can Find More Information," carefully before you invest in any of our securities.

Investing in our common shares involves risks. See "Risk Factors" beginning on page 7.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012, and as such, we have elected to take advantage of certain reduced public company reporting requirements for this prospectus and future filings.

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

The date of this prospectus is June 23, 2014

Table Of Contents

TABLE OF CONTENTS

We incorporate by reference important information into this prospectus. You may obtain the information incorporated by reference without charge by following the instructions under "Where You Can Find Additional Information." You should carefully read this prospectus as well as additional information described under "Incorporation of Certain Information by Reference," before deciding to invest in our common shares. All references in this prospectus to "Sophiris," "the Company," "we," "us" or "our" mean Sophiris Bio Inc., unless we state otherwise or the context otherwise requires.

We are responsible for the information contained in this prospectus. We have not authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

i

Table Of Contents

Summary

This summary highlights certain information about us, this offering and selected information contained in the prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common shares. For a more complete understanding of our company and this offering, we encourage you to read and consider the more detailed information in the prospectus, including "Risk Factors" and the financial statements and related notes. Unless we specify otherwise, all references in this prospectus to "Sophiris Bio" "we," "our," "us" and "our company" refer to Sophiris Bio Inc.

Sophiris Bio Inc.

Corporate Information

Our predecessor, Protox Pharmaceuticals Inc., was incorporated in January 2002. We were formed in May 2003 under the predecessor to the British Columbia Business Corporations Act, or the BCBCA, by the amalgamation of Stratos Biotechnologies Inc., Nucleus BioScience Inc. and Brightwave Ventures Inc. under the name SNB Capital Corp. In July 2004, we acquired all of the shares of Protox Pharmaceuticals Inc. in a plan of arrangement under the BCBCA and changed our name to Protox Therapeutics Inc. In January 2005, we amalgamated under the BCBCA with Protox Pharmaceuticals Inc. In April 2011, we announced the relocation of our core activities from Vancouver, British Columbia to San Diego, California in conjunction with the transition of a new senior management team. In connection with this operational realignment, we changed our name to Sophiris Bio Inc., effective April 2, 2012. On August 16, 2013, we commenced our U.S initial public offering and listing on the NASDAQ pursuant to a Registration Statement on Form S-1 (File No. 333-186724) that was declared effective by the Securities and Exchange Commission on August 16, 2013. On August 23, 2013, we sold 13,000,000 of our common shares to the public at a price of $5.00 per share for an aggregate gross offering price of $65 million. Our common shares are currently traded on the NASDAQ under the ticker symbol "SPHS."

Our principal executive office is located at 1258 Prospect Street, La Jolla, California 92037. Our telephone number is (858) 777-1760 and our facsimile number is (858) 412-5693. We are domiciled in Vancouver, British Columbia and our registered and records office is at 2900-550 Burrard Street, Vancouver, British Columbia, V6C 0A3. We also maintain a website at www.sophirisbio.com. The reference to our website is an inactive textual reference only and the information contained in, or that can be accessed through, our website is not part of this prospectus.

Sophiris, the Sophiris logo and other trademarks or service marks of Sophiris appearing in this prospectus are the property of Sophiris. This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of (1) December 31, 2018, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.0 billion, or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common shares that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (3) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the "JOBS Act," and references herein to "emerging growth company" shall have the meaning associated with it in the JOBS Act.

Table Of Contents

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

- only two years of audited financial statements needed for our initial registration (in addition to any required unaudited interim financial statements) and correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements;
- no requirement that we hold non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

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

Risk Factors

As a development stage biopharmaceutical company, we face many risks inherent in our business and our industry generally. You should carefully consider all of the information set forth in this prospectus and, in particular, the information under the heading "Risk Factors," prior to making an investment in our common shares. These risks include, among others, the following:

- We are an early stage company with no approved products and no revenue from commercialization of our product.
- Our limited operating history makes evaluating our business and future prospects difficult, and may increase the risk of any investment in our common shares.
- We are highly dependent on the success of PRX302 and we may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, this product candidate.

If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively in our market.

We will need to obtain additional financing to complete the development and commercialization of PRX302 and to repay existing debt and we may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our development program or commercialization efforts.

Table Of Contents

The Offering

Common shares being offered by the selling shareholder	3,409,629 shares
Common shares outstanding	16,844,736 (as of May 28, 2014)
Use of proceeds	The selling shareholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the selling shareholder. However, we may receive up to $15.0 million in proceeds from the sale of our common shares to the selling shareholder under the common stock purchase agreement described below. Any proceeds from the selling shareholder that we receive under the purchase agreement are expected be used for working capital and general corporate purposes.
NASDAQ Symbol	“SPHS”
Risk Factors	Investing in our securities involves a high degree of risk. You should carefully review and consider the “Risk Factors” section of this prospectus for a discussion of factors to consider before deciding to invest in our common shares.

On May 16, 2014, we entered into a common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, an Illinois limited liability company, or Aspire Capital or the selling shareholder, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $15.0 million of our common shares over the approximately 30-month term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 90,635 of our common shares as a commitment fee, referred to in this prospectus as the Commitment Shares. Upon execution of the Purchase Agreement, we sold to Aspire Capital 604,230 common shares, referred to in this prospectus as the Initial Purchase Shares. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital, referred to in this prospectus as the Registration Rights Agreement, in which we agreed to file one or more registration statements, including the registration statement of which this prospectus is a part, as permissible and necessary to register, under the Securities Act of 1933, as amended, or the Securities Act, the resale of our common shares that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of May 28, 2014, there were 16,149,871 of our common shares outstanding (0 shares held by non-affiliates) excluding the 3,409,629 shares offered that have been issued or may be issuable to Aspire Capital pursuant to the Purchase Agreement. If all of such 3,409,629 of our common shares offered hereby were issued pursuant to the Purchase Agreement, such shares would represent 21.1% of the total common shares outstanding or 21.1% of the non-affiliate shares of common shares outstanding as of the date hereof. However, pursuant to the Purchase Agreement, the number of shares that may be issued to Aspire Capital is limited to 3,228,359 shares (including the Commitment Shares and the Initial Purchase Shares), or the Exchange Cap, which equals 19.99% of the total common shares outstanding and the non-affiliate shares outstanding as of the date hereof, unless shareholder approval is obtained to issue more than the Exchange Cap or unless the average price paid for all shares issued under the Purchase Agreement is equal to or greater than $3.11 per share from an after the date that the Exchange Cap is reached. The number of our common shares ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering 694,865 of our common shares under the Securities Act, which includes the Commitment Shares and Initial Purchase Shares that have already been issued to Aspire Capital and 2,714,764 common shares which we may issue to Aspire Capital pursuant to this prospectus, such shares together with the Initial Purchase Shares referred to herein as the Purchase Shares. All 3,409,629 common shares are being offered pursuant to this prospectus.

Table Of Contents

On any trading day on which the closing sale price of our common shares exceeds $2.00, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice, each referred to as a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 100,000 of our common shares per trading day, provided that the aggregate price of such purchase shall not exceed $1,000,000 per trading day, up to $15.0 million of our common shares in the aggregate at a per share price, or the Purchase Price, which is equal to the lesser of: (i) the lowest sale price of our common shares on the purchase date; or (ii) the arithmetic average of the three lowest closing sale prices for our common shares during the ten consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which we submit a Purchase Notice for 100,000 shares to Aspire Capital and the closing sale price of our stock is greater than $2.00 per common share, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice, each referred to as a VWAP Purchase Notice, directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common shares traded on the NASDAQ on the next trading day, or the VWAP Purchase Date, subject to a maximum number of shares we may determine, or the VWAP Purchase Share Volume Maximum, and a minimum trading price, or the VWAP Minimum Price Threshold, which is equal to the greater of (a) 80% of the closing price of our common shares on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as set forth by us in the VWAP Purchase Notice. The VWAP Purchase Price of such shares is the lower of:

- the closing sale price on the VWAP Purchase Date; or
- 97% of the volume-weighted average price for our common shares traded on the NASDAQ :
  - on the VWAP Purchase Date, if the aggregate shares to be purchased on that date have not exceeded the VWAP Purchase Share Volume Maximum or
  - during that portion of the VWAP Purchase Date until such time as the sooner to occur of (i) the time at which the aggregate shares traded on the NASDAQ exceed the VWAP Purchase Share Volume Maximum or (ii) the time at which the sale price of our common shares falls below the VWAP Minimum Price Threshold.

The Purchase Agreement provides that we and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common shares is less than $2.00 per share, or the Floor Price. This Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common shares to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase

Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

Generally, Aspire Capital may terminate the Purchase Agreement upon the occurrence of any of the following events of default:

the effectiveness of any registration statement that is required to be maintained effective pursuant to the terms of the Registration Rights Agreement between us and Aspire Capital lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Aspire Capital for sale of our common shares, and such lapse or unavailability continues for a period of ten consecutive business days or for more than an aggregate of thirty business days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement; in connection with any post-effective amendment to such registration statement that is required to be declared effective by the SEC such lapse or unavailability may continue for a period of no more than 40 consecutive business days;

Table Of Contents

the suspension from trading or failure of our common shares to be listed on our principal market for a period of ten consecutive business days;

the delisting of our common shares from the NASDAQ, provided however, that in the event our common shares are not immediately thereafter listed and traded on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Select Market, the Nasdaq Global Market, Nasdaq Capital Market or the OTCQX market place of the OTC Markets,

our transfer agent's failure to issue to Aspire Capital our common shares which Aspire Capital is entitled to receive under the Purchase Agreement within five business days after an applicable purchase date;

any breach by us of the representations or warranties or covenants contained in the Purchase Agreement or any related agreements which could have a material adverse effect on us, subject to a cure period of five business days;

if we become insolvent or are generally unable to pay our debts as they become due; or

any participation or threatened participation in insolvency or bankruptcy proceedings by or against us.

The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of our common shares during any time prior to the termination of the Purchase Agreement.

The Purchase Agreement does not limit the ability of Aspire Capital to sell any or all of the 3,409,629 shares registered in this offering. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 30 months from the date of this prospectus. The sale by Aspire Capital of a significant amount of shares registered in this offering at any given time could cause the market price of our common shares to decline and/or to be highly volatile. Aspire Capital may ultimately purchase all, some or none of the 2,714,764 common shares not yet issued but registered in this offering. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Aspire Capital by us pursuant to the Purchase Agreement also may result in substantial dilution to the interests of other holders of our common shares. However, we have the right to control the timing and amount of any sales of our shares to Aspire Capital and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

5

Table Of Contents

In connection with entering into the Purchase Agreement, we authorized the sale to Aspire Capital of up to $15.0 million of our shares of common stock. However, we estimate that we will sell no more than 3,409,629 shares to Aspire Capital under the Purchase Agreement (including the Commitment Shares and the Initial Purchase Shares), all of which are included in this offering. Subject to any required approval by our board of directors, we have the right but not the obligation to issue more than the 3,409,629 shares included in this prospectus to Aspire Capital under the Purchase Agreement. In the event we elect to issue more than 3,409,629 shares under the Purchase Agreement, we will be required to file a new registration statement and have it declared effective by the SEC. The number of shares ultimately offered for sale by Aspire Capital in this offering is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement. The following table sets forth the number and percentage of outstanding shares to be held by Aspire Capital after giving effect to the sale of shares of common stock issued to Aspire Capital at varying purchase prices:

Assumed Average Purchase Price	**Proceeds from the Sale of Shares to Aspire Capital Under the Purchase Agreement Registered in this Offering (in millions)**	**Number of Shares to be Issued in this Offering at the Assumed Average Purchase Price (in millions) (1)**	**Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital (2)**
$3.00	$10.0	3.3	16%
$3.50	$11.6	3.3	16%
$4.00	$13.3	3.3	16%
$6.00	$15.0	2.5	13%
$8.00	$15.0	1.9	10%
$10.00	$15.0	1.5	8%

(1) Excludes 90,635 Commitment Shares issued under the Purchase Agreement between us and Aspire Capital.

(2) The denominator is based on 16,884,736 shares outstanding as of May 28, 2014, which includes the 694,865 shares previously issued to Aspire Capital and the number of shares set forth in the adjacent column which we would have sold to Aspire Capital. The numerator is based on the number of shares which we may issue to Aspire Capital under the Purchase Agreement (that are the subject of this offering) at the corresponding assumed purchase price set forth in the adjacent column.

As of June 23, 2013, all of the conditions necessary to the commencement of funding under the Purchase Agreement were satisfied.

Table Of Contents

RISK FACTORS

Investing in our common shares involves a high degree of risk. You should consider carefully the risks described below, together with all of the other information included in this prospectus, before deciding whether to invest in our common shares. The risks described below are material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually materialize, our business, prospects, financial condition, and results of operations could be seriously harmed. This could cause the trading price of our common shares to decline, resulting in a loss of all or part of your investment. The risks and uncertainties we describe are not the only ones facing us. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Business and Industry

We are an early stage company with no approved products and no revenue from commercialization of our product.

We are at an early stage of development of our product candidate, PRX302, for the treatment of the symptoms of benign prostatic hyperplasia, or BPH. We have not completed the development of any product candidates and, accordingly, have not begun to commercialize or generate any product revenues from any product candidate. PRX302 requires significant additional clinical testing and investment prior to seeking marketing approval. A commitment of substantial resources by ourselves and potential partners to conduct time-consuming Phase 3 clinical trials for PRX302 will be required to meet applicable regulatory standards, obtain required regulatory approvals, and to successfully commercialize this product candidate. PRX302 is not expected to be commercially available for several years, if at all.

We are highly dependent on the success of PRX302 and we may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, this product candidate.

To date, we have expended significant time, resources and effort on the development of PRX302, including conducting preclinical and clinical trials, for the treatment of the symptoms of BPH. We have no product candidates in our clinical development pipeline other than PRX302. Our ability to generate product revenues and to achieve commercial success in the near term will initially depend almost entirely on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize PRX302 in the United States and the European

Economic Area, or EEA. Before we can market and sell PRX302 in the United States or foreign jurisdictions, we will need to commence and complete additional clinical trials, manage clinical, preclinical, and manufacturing activities, obtain necessary regulatory approvals from the Food and Drug Administration, or FDA, in the United States and from similar foreign regulatory agencies in other jurisdictions, obtain manufacturing supply, build a commercial organization or enter into a marketing collaboration with a third party, and in some jurisdictions, obtain reimbursement authorization, among other things. We cannot assure you that we will be able to successfully complete the necessary preclinical studies and clinical trials and/or obtain regulatory approvals and sufficient commercial manufacturing supply for PRX302. If we do not receive regulatory approvals, our business, prospects, financial condition and results of operations will be adversely affected. Even if we obtain regulatory approvals, we may never generate significant revenues from any commercial sales of PRX302. If we fail to successfully commercialize PRX302, we may be unable to generate sufficient revenues to sustain and grow our business and our business, prospects, financial condition and results of operations will be adversely affected.

PRX302 is subject to extensive regulation, and we may not obtain regulatory approvals for PRX302.

The clinical development, manufacturing, labeling, packaging, storage, tracking, recordkeeping, advertising, promotion, export, import, marketing and distribution and other possible activities relating to our product candidate are, and for any other biologic or drug candidate that we may develop will be, subject to extensive regulation by the FDA in the United States and other regulatory agencies in foreign jurisdictions. PRX302, our only product candidate, is subject to regulation in the United States as a biologic. Biologics require the submission of a Biologics License Application, or BLA, and we are not permitted to market PRX302 in the United States until we obtain approval from the FDA of a BLA. To market PRX302 in the EEA, which includes the 27 member states of the European Union plus Norway, Liechtenstein and Iceland, we must submit a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, for approval under the EMA's centralized procedure, which if the marketing authorization is granted, will enable us to market the product throughout the entire territory of the EEA. A BLA or MAA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, sufficient to demonstrate the safety and effectiveness of the applicable product candidate to the satisfaction of FDA and EMA, respectively.

Table Of Contents

Regulatory approval of a BLA or an MAA is not guaranteed, and the approval process is expensive and will take several years. The FDA and foreign regulatory entities also have substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA or MAA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies or clinical trials or generate additional CMC data. The FDA, EMA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem our product candidate to be adequately safe and effective;
- may not find the data from our preclinical studies and clinical trials or CMC data to be sufficient to support a claim of safety and efficacy;
- may not approve the manufacturing processes or facilities associated with our product candidate;
- may conclude that we have not sufficiently demonstrated long-term stability of the formulation of the drug product for which we are seeking marketing approval;
- may change approval policies (including with respect to our product candidate's class of biologics) or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Obtaining approval of a BLA is a lengthy, expensive and uncertain process. As part of the U.S. Prescription Drug User Fee Act, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a BLA is 12 months from the filing date for a standard application and eight months from the filing date for a priority review application. The filing date is typically 60 days after submission of a BLA to the FDA. The FDA's review goals are subject to change, and it is unknown whether the review of a BLA for PRX302 will be completed within the FDA's target timelines or will be delayed. Moreover, the duration of the FDA's review may depend on the number and types of other BLAs that are submitted to the FDA around the same time period or are pending. Generally, public concern regarding the safety of drug products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

We submitted an investigational new drug application for PRX302 in April 2011. We have not submitted an application for approval or obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for PRX302. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements, either before or after product approval, may subject us to administrative or judicially imposed sanctions, including:

- warning letters;
- civil and criminal penalties;

- injunctions;
- withdrawal of approved products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production; and
- refusal to approve pending BLAs or supplements to approved BLAs.

Even if we believe that data collected from our preclinical studies and clinical trials of our product candidate are promising, our data may not be sufficient to support marketing approval by the FDA or any foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. In addition, the FDA's regulatory review of BLAs for product candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety, which may lead to increased scrutiny of the safety data we submit in our BLA for PRX302. Even if approved, a product candidate may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the biologic may be marketed, restricted distribution methods or other limitations. Our business and reputation may be harmed by any failure or significant delay in obtaining regulatory approval for the sale of our product candidate. We cannot predict when or whether regulatory approval will be obtained for any product candidate we develop.

To market any biologics outside of the United States, we and current or future collaborators must comply with numerous and varying regulatory and compliance related requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement and pricing approval in select markets. 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 associated with FDA approval as well as additional, presently unanticipated, 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 negatively impact the regulatory process in others, including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed.

Table Of Contents

The clinical trial protocol and design for our one ongoing and additional planned Phase 3 clinical trials of PRX302 may not be sufficient to allow us to submit a BLA to the FDA or demonstrate safety or efficacy at the level required by the FDA for product approval.

Based on the results from our Phase 2 clinical trials, we are currently conducting a Phase 3 clinical trial of PRX302 and expect to conduct one additional Phase 3 clinical trial for PRX302 to examine whether PRX302 will effectively relieve BPH symptoms as measured at three months and 12 months following treatment. The first of our two planned Phase 3 clinical trials, which we initiated in October 2013, will use the International Prostate Symptom Score, or IPSS, outcome measure evaluated at 12 months as the primary endpoint, which is consistent with clinical trials of another injectable currently under development by a third party for the treatment of the symptoms of BPH. We have not submitted a special protocol assessment, or SPA, which drug development companies sometimes use to obtain an agreement with the FDA concerning the design and size of a clinical trial intended to form the primary basis of an effectiveness claim. Without the concurrence of the FDA on an SPA or otherwise, we cannot be certain that the design, conduct and data analysis approach for our ongoing and planned Phase 3 clinical trials will generate data sufficient to establish the effectiveness of PRX302 for treatment of BPH symptoms to the FDA's satisfaction, and therefore allow us to submit or receive approval of a BLA for PRX302. If the FDA requires us, or we otherwise determine, to amend our protocols, change our clinical trial designs, increase enrollment targets or conduct additional clinical trials, our ability to obtain regulatory approval on the timeline we have projected would be jeopardized and we could be required to make significant additional expenditures related to clinical development.

Further, even if we achieve positive results on the endpoints for a clinical trial, the FDA may disagree with our interpretation of the data and deem the results insufficient to demonstrate efficacy at the level required by the FDA for product approval. It is possible that we may make modifications to the clinical trial protocols or designs of our ongoing and planned Phase 3 clinical trials that delay enrollment or completion of such clinical trials and could delay regulatory approval of PRX302. Any failure to obtain approval for PRX302 on the timeline that we currently anticipate, or at all, would have a material and adverse impact on our business, prospects, financial condition and results of operations.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized. Moreover, our business may be implicated if any of the relationships violate federal or state fraud and abuse laws or healthcare privacy and security laws.

Clinical development is a lengthy and expensive process with an uncertain outcome. Because the results of early clinical trials are not necessarily predictive of future results, PRX302 may not have favorable results in later clinical trials or receive regulatory approval.

Clinical development is expensive, takes many years to complete and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and PRX302 is subject to the risks of failure inherent in drug development. Success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing, even at statistically significant levels. We will be required to demonstrate through well-controlled clinical trials of PRX302 that our product candidate is safe and effective for use in its target indication before we can obtain regulatory approvals for its commercial sale.

Companies frequently suffer significant setbacks in late-stage clinical trials, even after earlier clinical trials have shown promising results. Either or both of our ongoing and planned Phase 3 clinical trials of PRX302 may not be successful for a variety of reasons, including faults in the clinical trial designs, the failure to enroll a sufficient number of patients, undesirable side effects and other safety concerns and the inability to demonstrate sufficient efficacy.

Table Of Contents

Further, the data collected from clinical trials with large patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of PRX302. Our one ongoing and additional planned Phase 3 clinical trials of PRX302 will enroll significantly more patients than we have enrolled in clinical trials of PRX302 to date. We are currently enrolling and expect to enroll approximately 440 patients in our first Phase 3 clinical trial. If PRX302 fails to demonstrate sufficient safety or efficacy, we would experience potentially significant delays in, or be required to abandon our development of, PRX302, which would have a material and adverse impact on our business, prospects, financial condition and results of operations.

PRX302 may cause undesirable side effects or have other properties that may delay or prevent its regulatory approval or commercialization or limit its commercial potential.

Undesirable side effects caused by PRX302 could cause us or regulatory authorities to interrupt, delay, suspend or terminate clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other regulatory authorities. This, in turn, could limit or prevent us from commercializing PRX302 and generating revenues from its sale. To date, the most common adverse events observed in patients who received PRX302 in our Phase 2 clinical trials that were potentially attributable to PRX302 included the presence of red blood cells in urine, painful urination, frequent urination and urinary urgency, perineal pain and discomfort (observed in patients who received both drug and placebo, which is otherwise referred to as the vehicle), vertigo and malaise that could be attributable to PRX302 induced inflammation. Each of the foregoing adverse events occurred in greater than 5% of the PRX302 population. Although none of the patients in our Phase 1/2 clinical trial using the transrectal route of administration experienced sepsis, our change to this route of administration is expected to increase the risk of sepsis. Results from our ongoing and planned Phase 3 clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of PRX302 for its targeted indication. Further, such side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may have a material and adverse impact on our business, prospects, financial condition and results of operations.

In addition, if PRX302 receives marketing approval and we or others later identify undesirable side effects caused by PRX302, a number of significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of PRX302;
- regulatory authorities may require that we demonstrate a larger clinical benefit by conducting additional clinical trials for approval to offset the risk;
- regulatory authorities may require the addition of labeling statements or warnings that could diminish the usage of the product or otherwise limit the commercial success of PRX302;
- we may be required to change the way PRX302 is administered;

- we may choose to recall, withdraw or discontinue sale of PRX302;
- we could be sued and held liable for harm caused to patients;
- we may not be able to enter into collaboration agreements on acceptable terms and execute on our business model; and
- our reputation may suffer.

Any one or a combination of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing PRX302, which in turn could delay or prevent us from generating any revenues from the sale of the product, which could significantly harm our business, prospects, financial condition and results of operations.

We may experience delays in the commencement or completion of our clinical trials, which could result in increased costs to us and delay our ability to pursue regulatory approval and generate product revenues.

Delays in the commencement or completion of clinical testing could significantly impact our product development costs and could result in the need for additional financing. Although we initiated the first of our two planned Phase 3 clinical trials in October 2013, we do not know when or whether our second planned Phase 3 clinical trials of PRX302 will begin, or if either trial will be completed on time, or at all. The commencement or completion of clinical trials can be delayed for a variety of reasons, including delays in or related to:

- raising sufficient capital to fund our second planned Phase 3 clinical trial;
- obtaining regulatory approval, or feedback on trial design necessary, to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- identifying, recruiting and enrolling suitable patients to participate in a clinical trial;
- catastrophic loss of drug product due to shipping delays or delays in customs in connection with delivery of drug product to foreign countries for use in clinical trials;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining sufficient quantities of PRX302 and the diluent used with PRX302 for use in clinical trials;
- having patients complete a trial or return for post-treatment follow-up;

Table Of Contents

- adding new clinical trial sites;
- political unrest in countries where our clinical sites maybe located;
- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions;
- unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;
- obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site; and
- retaining patients who have initiated a clinical trial but may withdraw due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues.

Any delays in the commencement or completion of our clinical trials will delay our timeline to obtain regulatory approval for our product candidate. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval for a product candidate. Our one ongoing and additional planned Phase 3 clinical trials of PRX302 for the treatment of the symptoms of BPH will seek to enroll significantly more patients than we have enrolled in clinical trials of PRX302 to date. We are currently enrolling and expect to enroll approximately 440 patients in our first Phase 3 clinical trial both in and outside of the United States. We do not expect to commence enrollment of our second Phase 3 clinical trial until completion of an administrative analysis by an independent data monitoring committee conducted once all patients have completed three months in the first Phase 3 clinical trial.

We may face competition to enroll BPH patients in our ongoing and planned Phase 3 clinical trials from other clinical trials for other sponsors including potential competitors. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Delays in enrollment in our ongoing and planned Phase 3 clinical trials of PRX302 would result in delays in our ability to pursue regulatory approval of PRX302.

Changes in regulatory requirements and guidance also may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing and successful completion of a clinical trial. If we experience delays in the completion of, or if we must terminate, any clinical trial of PRX302, our ability to obtain regulatory approval for that product candidate will be delayed and the commercial prospects, if any, for the product candidate may be harmed. If we ultimately commercialize PRX302, other therapies for the same indications may have been introduced to the market during the period we have been delayed and such therapies may have established a competitive advantage over our product candidates.

We expect to rely upon multiple CROs to conduct and oversee our ongoing and planned Phase 3 clinical trials for PRX302. If any of our CROs does not meet our deadlines or otherwise conduct the trials as required or if any CRO experiences regulatory compliance issues we may not be able to obtain regulatory approval for or commercialize our product candidate when expected or at all.

We have entered into agreements with multiple CROs for our first Phase 3 clinical trial of PRX302. We also rely upon medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and in accordance with applicable legal and regulatory requirements. These third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. There is no guarantee that any such third party will devote adequate time and resources to our clinical trial. If any of our CROs or any other third parties upon which we rely for administration and conduct of our clinical trials do not successfully carry out their contractual duties or obligations or fail to meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or if they otherwise perform in a substandard manner, our clinical trials may be extended, delayed, suspended or terminated, and we may not be able to complete development of and ultimately obtain approval for and successfully commercialize PRX302. We will rely heavily on these third parties for the execution of our ongoing and planned Phase 3 clinical trials and will control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with current Good Clinical Practice, or GCP, which are regulations and guidelines enforced by the FDA, the competent authorities of the Member States of the EEA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with applicable GCP regulations. In addition, our clinical trials must be conducted with product produced under the current Good Manufacturing Practice, or cGMP, regulations enforced by the FDA, and our clinical trials require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Table Of Contents

If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trial unless we are able to transfer the care of those patients to another qualified clinical trial site. Further, if our relationship with any of our CROs is terminated, we may be unable to enter into arrangements with alternative CROs on commercially reasonable terms, or at all.

Switching or adding CROs can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationship with our CROs, there can be no assurance that we will not encounter such challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition or results of operations.

Any adverse developments that occur during any clinical trials conducted by Kissei may affect our ability to obtain regulatory approval or commercialize PRX302.

Kissei Pharmaceutical Co., Ltd., or Kissei, retains the rights to develop and commercialize PRX302 in Japan for the treatment of the symptoms of BPH, prostate cancer, prostatitis or other diseases of the prostate. If serious adverse events occur during this or any other clinical trials Kissei decides to conduct with respect to PRX302, the FDA and other regulatory authorities may delay, limit or deny approval of PRX302 or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive FDA approval for PRX302 and a new and serious safety issue is identified in connection with clinical trials conducted by Kissei, the FDA and other regulatory authorities may withdraw their approval of the product or otherwise restrict our ability to market and sell our product. In addition, treating physicians may be less willing to administer our product due to concerns over such adverse events, which would limit our ability to commercialize PRX302.

Our limited operating history makes evaluating our business and future prospects difficult, and may increase the risk of any investment in our common shares.

Our predecessor, Protox Pharmaceuticals Inc., was incorporated in January 2002. We were formed in May 2003 under the predecessor to the British Columbia Business Corporations Act, or the BCBCA, by the amalgamation of Stratos Biotechnologies Inc., Nucleus BioScience Inc. and Brightwave Ventures Inc. under the name SNB Capital Corp. In July 2004, we acquired all the shares of Protox Pharmaceuticals Inc. in a plan of arrangement under the BCBCA and changed its name to Protox Therapeutics Inc. In 2011, we formed a wholly-owned U.S. subsidiary incorporated in Delaware, Protox Therapeutics Corp. In 2012, we changed our name to Sophiris Bio Inc. and changed the name of our subsidiary to Sophiris Bio Corp. In 2012, Sophiris Bio Corp. formed a wholly-owned subsidiary incorporated in Delaware, Sophiris Bio Holding Corp. We face considerable risks and difficulties as a company with limited operating history, particularly as a consolidated entity with an operating subsidiary that also has a limited operating history. If

we do not successfully address these risks, our business, prospects, operating results and financial condition will be materially and adversely harmed. Our limited operating history makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected. We have limited experience as a consolidated operating entity, and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical or biotechnology areas.

We face significant competition from other pharmaceutical and biotechnology companies and from minimally invasive surgical therapies and surgical alternatives, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and international markets, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective, easier to administer and/or less costly than PRX302.

Table Of Contents

We expect that PRX302 will compete with the current treatment options for the symptoms of BPH, which include oral drug therapy and surgery. Oral drug therapies include (a) a-blockers, such as tamsulosin (marketed under various trade names by numerous companies, including as Flomax® by Astellas Pharma), alfuzosin (marketed in the United States by Sanofi as Uroxatral®), doxazosin (marketed by Pfizer as Cardura® and Cardura® XL) and silodosin (marketed by Watson Pharmaceuticals as Rapaflo® in the United States), (b) 5-a reductase inhibitors, such as dutasteride (marketed by GlaxoSmithKline plc as Avodart®) and finasteride (marketed by Merck & Co., Inc. as Proscar®), (c) combinations of a-blockers and 5-a reductase inhibitors such as tamsulosin and dutasteride (marketed by GSK as Jalyn®) and (d) tadalafil (marketed as Cialis® by Eli Lilly), a PDE5 inhibitor which obtained FDA approval for the treatment of the symptoms of BPH in October 2011. Several minimally invasive surgical therapies, or MIST, are available, including transurethral microwave thermotherapy, or TUMT, transurethral needle ablation, or TUNA, photo-selective vaporization of prostate, holmium laser enucleation of the prostate, transurethral electrovaporization of the prostate, interstitial laser coagulation, and the UroLift® system (marketed by NeoTract, Inc.), which is an implant delivered into the body via a small needle and designed to hold prostate tissue out of the way of the blocked urethra.

Currently, the most commonly used MIST procedures are laser ablations of the prostate, TUMT, and TUNA. Surgery for BPH treatment is usually considered in patients who fail drug therapy as a result of side effects or inadequate relief of symptoms, have refractory urinary retention, or have recurrent urinary tract infections. Alternatively, surgery may be the initial treatment in patients with severe urinary symptoms. Surgical procedures for BPH include transurethral resection of the prostate, as well as other procedures such as transurethral incision of the prostate and transurethral vaporization of the prostate.

The availability and price of our competitors' products and procedures could limit the demand, and the price we are able to charge, for PRX302. We will not successfully execute on our business objectives if the market acceptance of PRX302 is inhibited by price competition, if physicians are reluctant to switch from existing products or procedures to PRX302 or if physicians switch to other new products or surgeries or choose to reserve PRX302 for use in limited patient populations. In addition, established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license and develop novel compounds that could make PRX302 obsolete.

Any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to be approved and overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, obtaining FDA approval or discovering, developing and commercializing products before we do, which would have a material adverse impact on our business. The inability to compete with existing products or subsequently introduced products would have a material adverse impact on our business, prospects, financial condition and results of operations.

Even if we obtain and maintain approval for PRX302 from the FDA, we may never obtain approval for PRX302 outside of the United States, which would limit our market opportunities and adversely affect our business.

Sales of PRX302 outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries must also approve the manufacturing and marketing of the product candidates in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to approval. We may decide to submit an MAA to the EMA for approval in the EEA. As with the FDA, obtaining approval of an MAA from the EMA is a similarly lengthy and expensive process and the EMA has its own procedures for approval of product candidates. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the EEA also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of PRX302 will be harmed and our business will be adversely affected.

Table Of Contents

We will be, with respect to any product candidate for which we obtain FDA approval, subject to ongoing FDA obligations and continued regulatory review, which may result in significant additional expense.

Any regulatory approvals that we obtain for our product candidate may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including post-marketing studies and clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable foreign regulatory authority, like the EMA, approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, tracking and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs for marketed drugs and drugs used in clinical trials and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions, the imposition of civil or criminal penalties, or exclusions.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would have a material adverse effect on our business, prospects, financial condition and results of operations.

Moreover, the recently enacted federal Drug Supply Chain Security Act, imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new federal legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are

otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

We will need to increase the size of our organization and the scope of our outside vendor relationships, and we may experience difficulties in managing growth.

As of March 31, 2014 we had ten full-time employees. In addition, we have engaged part-time individual consultants to assist us with establishing accounting systems, managing vendors and CROs, project management, regulatory compliance and business development. We will need to expand our managerial, operational, financial and other resources in order to manage our operations and clinical trials, continue our research and development activities, and commercialize our product candidate. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- manage our clinical trials effectively, including our two planned Phase 3 clinical trials of PRX302;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors and other third parties;
- continue to improve our operational, financial and management controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees; and
- manage our regulatory compliance oversight and infrastructure.

To date, we have utilized the services of third-party vendors to perform tasks including clinical trial management, statistics and analysis, regulatory affairs, formulation development and other drug development functions. Our growth strategy may also entail expanding our group of contractors or consultants to implement these tasks going forward. Because we rely on numerous consultants, effectively outsourcing many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidate or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may be unable to successfully implement the tasks necessary to further develop and commercialize our product candidate and, accordingly, may not achieve our research, development and commercialization goals.

Table Of Contents

The terms of our senior debt facility require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In July 2011, we entered into a $15 million senior secured loan with Oxford Finance LLC, or Oxford, which, as amended, we refer to as the Oxford Loan. The Oxford Loan is secured by a lien covering all of our assets, including intellectual property, and we also pledged as collateral all of our equity interests in Sophiris Bio Corp. and Sophiris Bio Holding Corp. We are obligated to make monthly payments of principal and interest through the maturity date of November 1, 2014, assuming there is no default that results in acceleration of the debt. In connection with the Oxford Loan, we entered into an investment letter agreement, or the Investment Letter, with Oxford, which grants Oxford the right to purchase up to $1 million of specified securities in connection with a qualified financing involving the private sale of our common shares or common-convertible securities through October 2014, subject to additional restrictions described in the Investment Letter.

The loan agreement governing the Oxford Loan contains customary affirmative and negative covenants, indemnification provisions and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain certain intellectual property rights. The negative covenants include, among others, restrictions on transferring or licensing our assets, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on our assets, in each case subject to customary exceptions. If we default under the Oxford Loan, Oxford may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, Oxford's right to repayment would be senior to the rights of the holders of our common shares to receive any proceeds from the liquidation. Oxford could declare a default under the Oxford Loan upon the occurrence of any event that Oxford interprets as a material adverse change as defined under the loan agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by Oxford of an event of default could significantly harm our business and prospects and could cause the price of our common shares to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

We rely on third parties to manufacture PRX302 and an ingredient used in the diluent used to administer PRX302, and we intend to rely on third parties to manufacture commercial supplies of PRX302, if and when it is approved. The development and commercialization of PRX302 could be stopped or delayed if any such third party fails to provide us with sufficient quantities of the product or the diluent or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to

manufacture PRX302 on a clinical or commercial scale. Instead, we rely on our third-party manufacturing partner, Boehringer Ingleheim RCV GmbH & Co KG, or BI, located in Austria, for the production of PRX302 and BI Germany for fill and testing services pursuant to an agreement which we entered into in 2011. BI currently procures an ingredient used in the formulation of PRX302 from a multinational industrial biotech company which is a single source supplier, on a purchase order basis. The facilities used by our third-party manufacturer to manufacture PRX302 and any other potential product candidates that we may develop in the future must be approved by the applicable regulatory authorities, including the FDA, pursuant to inspections that will be conducted after we submit our BLA to the FDA. We do not control the manufacturing processes of BI and are currently completely dependent on BI for the production of PRX302 in accordance with cGMPs, which include, among other things, quality control, quality assurance and the maintenance of records and documentation.

Although we have entered into an agreement for the manufacture of clinical supplies and initial commercial supplies of PRX302, BI may not perform as agreed, may be unable to comply with these cGMP requirements and with FDA, state and foreign regulatory requirements or may terminate its agreement with us. Moreover, we have not entered into a commercial supply agreement with BI and BI has not demonstrated that it will be capable of manufacturing PRX302 on a large commercial scale. Further, if our single source provider is unable to or decides to no longer supply BI or us with an ingredient for the diluent, we could experience delays in obtaining product for clinical trials until we procured another source or until we reformulate the product and we may be required to contract with another source in order to assure adequate commercial supply. Reformulation could result in significant further delays as we would be required to conduct additional clinical trials.

Table Of Contents

If our third-party manufacturer cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of any third-party manufacturer to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve these facilities for the manufacture of our products or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturer decide they no longer want to supply our biologic or manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products. We might be unable to identify manufacturers for long-term commercial supply on acceptable terms or at all. Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and other governmental authorities to ensure strict compliance with government regulations. Currently, our contract manufacturer is located outside the United States and the FDA has recently increased the number of foreign drug manufacturers which it inspects. As a result, our third-party manufacturer may be subject to increased scrutiny.

If we were to experience an unexpected loss of PRX302 supply, we could experience delays in our ongoing and planned Phase 3 clinical trials as BI would need to manufacture additional PRX302 and would need sufficient lead time to schedule a manufacturing slot. This is due to the fact that, given its nature, PRX302 cannot be manufactured in the BI facility at the same time as other biologics.

PRX302 is manufactured by starting with cells which are stored in a cell bank. We have one master cell bank and multiple working cell banks and believe we would have adequate backup should any cell bank be lost in a catastrophic event. However, it is possible that we could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks.

The manufacture of biopharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and our contract manufacturers must comply with cGMP regulations and guidelines. Manufacturers of biopharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of any of our products will not occur in the future. Additionally, our manufacturer may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturer were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide any product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Any adverse developments affecting clinical or commercial manufacturing of our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, the need to reformulate our product or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our products or product candidates and could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our ability to generate revenues from PRX302 will be subject to attaining significant market acceptance among physicians, patients and healthcare payers.

PRX302, if approved, may not attain market acceptance among physicians, patients, healthcare payers or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from PRX302 will depend on a number of factors, including:

- timing of market introduction of our products as well as competitive drugs;
- efficacy and safety of PRX302;
- the clinical indication(s) for which PRX302 is approved;
- continued projected growth of the urological disease markets, including incidence of BPH;
- acceptance by patients, primary care specialists and key specialists, including urologists;
- potential or perceived advantages or disadvantages of PRX302 over alternative treatments, including cost of treatment and relative convenience and ease of administration and length of sustained benefits from treatment;
- strength of sales, marketing and distribution support;
- the price of PRX302, both in absolute terms and relative to alternative treatments;

Table Of Contents

- the effect of current and future healthcare laws;
- availability of coverage and adequate coverage, reimbursement and pricing from government and other third-party payers; and
- product labeling or product insert requirements of the FDA or other regulatory authorities.

If PRX302 is approved but fails to attain market acceptance by physicians, patients, health care payers, or the medical community, we may not be able to generate significant revenue to achieve or sustain profitability, which would have a material adverse effect on our business, prospects, financial condition and results of operations.

Coverage and reimbursement may not be available, or may be available at only limited levels, for PRX302, which could make it difficult for us to sell PRX302 profitably.

Market acceptance and sales of PRX302 will depend in large part on global reimbursement policies and may be affected by future healthcare reform measures, both in the United States and other key international markets. Patients who are prescribed medicine for the treatment of their conditions generally rely on third party payers to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Therefore, successful commercialization of our product will depend in part on the availability of governmental and third-party payer reimbursement for the cost of PRX302 and/or payment to the physician for administering PRX302. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payers. Therefore, coverage and reimbursement for drug products can differ significantly from payer to payer. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained. One third-party payer's decision to cover a particular medical product or service does not assure that other payers will also provide coverage for the medical product or service, or to provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that adequate coverage and reimbursement will be obtained. Further, a third-party payer's decision to provide coverage for a medical product or service does not imply that an adequate reimbursement rate will be approved. The market for our product candidates will depend significantly on access to third-party payers' formularies, or lists of treatments for which third-party payers provide coverage and reimbursement.

Government health administration authorities, private health insurers and other organizations establish coverage and reimbursement policies for new products, including product candidates like PRX302. In particular, in the United States, private health insurers and other third-party payers often provide reimbursement for treatments based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the United States, the EEA and other significant or potentially significant markets for our product candidate, government authorities and third-party payers are increasingly attempting to limit or regulate the price of

medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in Canada and the EEA will put additional pressure on product pricing, coverage, reimbursement and utilization, which may adversely affect our product sales and results of operations. These pressures can arise from policies and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, coverage and reimbursement policies and pricing in general. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of PPACA of greatest importance to the pharmaceutical industry are the following: (i) an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs; (ii) an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively; (iii) a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (iv) extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (v) expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability; (vi) expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; (vii) expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance; and (viii) a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. We cannot predict whether legal challenges will result in changes to the PPACA or if other legislative changes will be adopted, or how such changes would affect our business.

Table Of Contents

In the EEA, the success of PRX302, if approved, will depend largely on obtaining and maintaining government reimbursement, because in many European countries patients are unlikely to use therapies that are not reimbursed by the government. Negotiating prices with governmental authorities can delay commercialization by 12 months or more. Reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently, many countries in the EEA have increased the amount of discounts required on pharmaceutical products and other therapies, and we expect these discounts to continue as countries attempt to manage healthcare expenditures, especially in light of current economic conditions. As a result of these pricing practices, it may become difficult to achieve profitability or expected rates of growth in revenue or results of operations. Any shortfalls in revenue could adversely affect our business, prospects, financial condition and results of operations.

Certain countries have a very difficult reimbursement environment and we may not obtain reimbursement or pricing approval, if required, in all countries where we expect to market a product, or we may obtain reimbursement approval at a level that would make marketing a product in certain countries not viable

We expect to experience pricing pressures in connection with the sale of PRX302, if approved, and any other products that we may develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain adequate coverage and reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and expected revenue and profitability which would have a material adverse effect on our business, prospects, financial condition and results of operations.

Our failure to successfully acquire, develop and market additional product candidates or approved products could impair our ability to grow.

As part of our growth strategy, we may acquire, develop and/or market additional products and product candidates. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical product candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and

technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

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

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured profitably or achieve market acceptance.

Table Of Contents

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors and consultants and collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture PRX302 and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidate could be delayed.

Business interruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, systems failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business interruptions could seriously harm our business and financial condition and increase our costs and expenses. A majority of our management operates in our principal executive offices located in San Diego, California. If our San Diego offices were affected by a natural or man-made disaster, particularly those that are characteristic of the region, such as wildfires and earthquakes, or other business interruption, our ability to manage our domestic and foreign operations could be impaired, which could materially and adversely affect our results of operations and financial condition. We currently rely, and intend to rely in the future, on our third-party manufacturer, BI, which is located in Austria and Germany, to produce our supply of PRX302. Our ability to obtain supplies PRX302 could be disrupted, and our results of operations and financial condition could be materially and adversely affected if the operations of BI were affected by a man-made or natural disaster or other business interruption. The ultimate impact of such events on us, our significant suppliers and our general infrastructure is unknown.

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

Our third-party manufacturer’s activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of PRX302 and other hazardous compounds. Specifically, the cleavage of the

PSA-sensitive activation sequence of PRX302 in the manufacturing process could potentially lead to the release of the C-terminal inhibitory peptide resulting in the formation of active aerolysin, a pore-forming hemolytic toxin. We and our manufacturer are subject to federal, state and local as well as foreign laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures utilized by our third-party manufacturer for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. BI, our third-party manufacturer, does not manufacture PRX302 in its facility at the same time as it manufactures other biologics due to the toxic nature of aerolysin. In the event of an accident, state, federal or foreign authorities may curtail the use of these materials and interrupt our business operations. We do not currently maintain hazardous materials insurance coverage. If we are subject to any liability as a result of our third-party manufacturer's activities involving hazardous materials, our business and financial condition may be adversely affected. In the future we may seek to establish longer term third-party manufacturing arrangements, pursuant to which we would seek to obtain contractual indemnification protection from such third-party manufacturers potentially limiting this liability exposure.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We face an inherent risk of product liability as a result of the clinical testing and, if approved, the commercialization of PRX302. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state or foreign consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidate. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product or product candidates that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;

Table Of Contents

- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products or product candidates; and
- a decline in our share price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies and commercial product sales in the amount of $10 million in the aggregate.

Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of any product, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and scientific and medical personnel, including our Executive Chairman, Lars Ekman, M.D., Ph.D., our Chief Executive Officer and President, Randall E. Woods, and our Chief Operating Officer and Head of Research and Development, Allison Hulme, Ph.D. In order to retain valuable employees at our company, in addition to salary

and cash incentives, we provide incentive stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Our scientific team in particular has expertise in many different aspects of drug discovery and development, and may be difficult to retain or replace. We conduct our operations at our facilities in San Diego, California and this region is headquarters to many other biopharmaceutical companies and many academic and research institutions and therefore we face increased competition for personnel in this location. Competition for skilled personnel in our market is very intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms.

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

Despite our efforts to retain valuable employees, members of our management and scientific and development teams may terminate their employment with us on short notice. Although we have written employment arrangements with all of our employees, these employment arrangements provide for at-will employment, which means that our employees can leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar regulatory bodies; provide true, complete and accurate information to the FDA and other similar regulatory bodies; comply with manufacturing standards we have established; comply with federal and state healthcare fraud and abuse laws and other similar foreign fraudulent misconduct laws; or report financial information or data accurately or disclose unauthorized activities to us. These laws may impact, among other things, our activities with principal investigators and research subjects, as well as our sales, marketing and education programs. In particular, the promotion, sales, and marketing of health care items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Misconduct could also involve the improper use or disclosure of information obtained in the course of clinical trials, which could result in regulatory sanctions and

serious harm to our reputation. Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, some of which may be broader in scope and may apply regardless of the payer.

Table Of Contents

We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell any products we may develop, we may not be able to effectively market and sell our products and generate product revenue.

We are developing PRX302 for large patient populations served by urologists as well as general practice physicians, which number in the tens of thousands in the United States. Traditional pharmaceutical companies employ groups of sales representatives numbering in the thousands to call on this large of a number of physicians. We do not currently have an organization for the sale, marketing or distribution of PRX302 and we must build this organization or make arrangements with third parties to perform these functions in order to commercialize PRX302 and any future products. We intend to establish (either internally or through a contract sales force) a sales force to sell PRX302, if approved, in the United States. We plan to partner with third parties to commercialize PRX302 outside the United States. The establishment and development of our own sales force or the establishment of a contract sales force to market any products we may develop in the United States will be expensive and time consuming and could delay any product launch, and we cannot be certain that we would be able to successfully develop this capacity. If we are unable to establish our sales and marketing capability or any other non-technical capabilities necessary to commercialize any products we may develop, we will need to contract with third parties to market and sell such products in the United States. We currently possess limited resources and may not be successful in establishing our own internal sales force or in establishing arrangements with third parties on acceptable terms, if at all.

Risks Related to Our Financial Position and Capital Requirements

We will need to obtain additional financing to complete the development and commercialization of PRX302 and to repay existing debt and we may be unable to raise capital when needed, which would force us to delay, reduce or

eliminate our development program or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. Since inception, we have raised approximately $111 million from the sale of equity securities in private placements and public offerings as well as approximately $9 million from the exercise of common share purchase warrants. In July 2011, we entered into the Oxford Loan for $15 million, which we are repaying over a 39-month period.

We expect to continue to spend substantial amounts to repay our Oxford Loan, to continue clinical development, including the conduct of our planned Phase 3 clinical trials and any future required clinical development, and seek regulatory approval for PRX302, and to launch and commercialize PRX302, if approved.

We expect that our existing cash, together with interest thereon, will be sufficient to fund our operations for at least the next 12 months. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. For example, our ongoing or planned Phase 3 clinical trial may encounter technical, enrollment or other issues that could cause our development costs to increase more than we expected. In any event, we expect that we will require additional capital to complete development of PRX302, including completion of both of our planned Phase 3 clinical trials, and to obtain regulatory approval of and to commercialize PRX302.

Table Of Contents

The extent to which we utilize the Purchase Agreement with Aspire Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the Purchase Agreement on any given day and during the term of the agreement is limited. See "The Offering" section of this prospectus for additional information. Additionally, we and Aspire Capital may not effect any sales of shares of our common stock under the Purchase Agreement during the continuance of an event of default or on any trading day that the closing sale price of our common stock is less than $2.00 per share. Even if we are able to access the full $15.0 million under the Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans.

We expect to finance future cash needs through public or private equity offerings, debt financings or strategic partnerships and alliances and licensing arrangements, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. Subject to limited exceptions, the Oxford Loan also prohibits us from incurring indebtedness without the prior written consent of Oxford. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of PRX302. We also could be required to:

- seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common shares to decline.

We have incurred significant operating losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

We have a limited operating history and we have financed our operations primarily through equity and debt financings and have incurred significant operating losses since our inception. We had a net loss of $11.1 million, $21.2 million, and $14.2 million during the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of $84.8 million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' deficit and working capital. Our losses have resulted principally from costs incurred in our research activities for PRX302. We anticipate that our operating losses will substantially increase over the next several years as we continue development of PRX302, including the conduct of our ongoing and planned Phase 3 clinical trials. In addition, if we obtain regulatory approval of PRX302, we may incur significant sales and marketing expenses and outsourced manufacturing expenses, as well as continued development expenses. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or whether or when we will become profitable.

We have not generated any product revenue and may never become profitable.

Our ability to become profitable depends upon our ability to develop and commercialize PRX302. To date, other than the upfront payment we received from Kissei and the $5.0 million milestone payment we received in April 2013 from Kissei for the achievement of development milestones, we have not generated any revenue from PRX302 and we do not know when, or if, we will generate any future revenue. Our ability to generate future revenue depends on a number of factors, including:

- successfully completing our ongoing and planned Phase 3 clinical trials for PRX302;
- obtaining U.S. and/or foreign regulatory approvals for PRX302;
- manufacturing commercial quantities of PRX302 at acceptable costs levels if regulatory approvals are received;
- achieving broad market acceptance of PRX302 in the medical community and with third-party payors and patients; and
- creating an internal commercial infrastructure or identifying and entering into one or more strategic collaborations to effectively market and sell PRX302.

We may never be able to successfully develop or commercialize PRX302. Even if we do obtain regulatory approval to commercialize PRX302, which we do not expect to occur for several years, we may never generate product sales and may never achieve or sustain profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our common shares and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

Table Of Contents

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish intellectual property rights to our product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our shareholders. Debt financings may be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing shareholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

We have broad discretion in the use of the net proceeds from our initial public offering and may not use them effectively.

Our management has broad discretion in the application of the net proceeds from our initial public offering, or IPO. Because of the number and variability of factors that will determine our use of the net proceeds from our IPO, their ultimate use may vary substantially from their currently intended use. Our management may not apply our cash from our IPO in ways that ultimately increase the value of any investment in our securities. The failure by our management to apply these funds effectively could harm our business. We have invested the net proceeds from our IPO in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our shareholders. If we do not invest or apply our cash in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause the price of our common shares to decline.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more

dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At March 31, 2014, we had $18.6 million of cash and cash equivalents and $21.6 million in securities available-for-sale. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents since March 31, 2014, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of cash equivalents owned by us.

Fluctuations in foreign currency exchange rates could result in changes in our reported revenues and earnings.

We currently incur expenses denominated in foreign currencies, specifically in connection with our manufacturing and supply agreement with Boehringer Ingelheim RCV GmbH & Co KG for the manufacture of PRX302, for which payments are denominated in euro. In addition, we expect that we will utilize numerous clinical trial sites as part of our first Phase 3 clinical trial for PRX302 which will be located in various countries outside of the United States. We expect that these clinical trial sites will invoice us in the local currency of the site. We do not engage in foreign currency hedging arrangements for our accounts payable, and, consequently, foreign currency fluctuations may adversely affect our earnings. During the three months ended March 31, 2014 and 2013, 33.4% and 20%, respectively, of our operating expenses were denominated in currencies other than the U.S. dollar. Going forward we anticipate that our sales and expenses, if any, will be denominated in the local currency of the country in which they occur. We may decide to manage this risk by hedging our foreign currency exposure, principally through derivative contracts. Even if we decide to enter into such hedging transactions, we cannot be sure that such hedges will be effective or that the costs of such hedges will not exceed their benefits. Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies, primarily the euro, could result in material amounts of cash being required to settle the hedge transactions or could adversely affect our financial results.

Table Of Contents

Risks Related to our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in Canada, the United States or in other foreign countries. If this were to occur, early generic competition could be expected against product candidates in development. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated.

Composition-of-matter patents on the biological or chemical active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our patent applications covering composition-of-matter of PRX302 will be considered patentable by the U.S. Patent and Trademark Office, or U.S. PTO, and courts in the United States or by the patent offices and courts in foreign countries. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products off-label. Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to PRX302 fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them, and threaten our ability to commercialize, our products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals, the period of time during which we could market PRX302 under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to PRX302. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

The Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law in September 2011 and includes a number of significant changes to U.S. patent law. These include changes in the way patent applications will be prosecuted and may also affect patent litigation. The U.S. PTO is currently developing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the cost of prosecuting our patent applications, our ability to obtain patents based on our patent applications and our ability to enforce or defend our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States and Canada. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Table Of Contents

Third party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the U.S. PTO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we, and our collaborators, are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of PRX302. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. We are aware of at least one third-party patent that may be relevant to our product candidates. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, we could lose license rights that are important to our business.

We are a party to a number of technology licenses that are essential to our business and expect to enter into additional licenses in the future. For example, we have an exclusive license to PRX302 from UVIC Industry Partnerships Inc. and The Johns Hopkins University. If we fail to comply with our obligations under that license agreement or our other license agreements, or we are insolvent or subject to a bankruptcy proceeding, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license agreement, including PRX302. We may also be subjected to litigation or other potential disputes under our license agreements if we fail to comply with our obligations under those agreements.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors 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 patents do not cover the technology in question. An adverse result in any litigation or defense 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 proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Table Of Contents

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common shares.

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

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

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, including China, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, 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 product candidates 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.

Table Of Contents

Risks Related to Ownership of Our Common Shares

U.S. holders of our shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company after 2012.

Generally, if for any taxable year 75% or more of our gross income is passive income, or at least 50% of the average quarterly value of our assets (which may be determined in part by the market value of our ordinary shares, which is subject to change) are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company, or PFIC, for United States federal income tax purposes. Based on the composition of our gross income and gross assets and the nature of our business, we expect that we were a PFIC for the taxable year ending December 31, 2012 and that we may be a PFIC for the taxable year ending December 31, 2013. In 2014 and for future years, our status as a passive foreign investment company will also depend on whether we are a "controlled foreign corporation" for U.S. federal income tax purposes, how quickly we utilize the cash proceeds from our IPO in our business and other factors. If we are a PFIC for 2013 or any subsequent year, U.S. holders of our shares may suffer adverse tax consequences. Gains realized by non-corporate U.S. holders on the sale of our ordinary shares would be taxed as ordinary income, rather than as capital gain, and the preferential tax rate applicable to dividends received on our ordinary shares would be lost. Interest charges would also be added to taxes on gains and dividends realized by all U.S. holders.

A U.S. holder may avoid these adverse tax consequences by timely making a qualified electing fund election. For each year that we would meet the PFIC gross income or asset test, an electing U.S. holder would be required to include in gross income its pro rata share of our net ordinary income and net capital gains, if any. A U.S. holder may make a qualified electing fund election only if we commit to provide U.S. holders with their pro rata share of our net ordinary income and net capital gains. Because we intend to provide this information, a U.S. holder should be eligible to make a qualified electing fund election.

A U.S. holder may also mitigate the adverse tax consequences of being a PFIC by timely making a mark-to-market election. Generally, for each year that we would meet the PFIC gross income or asset test, an electing U.S. holder would include in gross income the increase in the value of its shares during each of its taxable years and deduct from gross income the decrease in the value of such shares during each of its taxable years. A mark-to-market election may be made and maintained only if our shares are regularly traded on a qualified exchange. While we anticipate that these requirements will be satisfied following our IPO, whether our shares are regularly traded on a qualified exchange is an annual determination based on facts that, in part, are beyond our control. Accordingly, we can provide no assurances that a U.S. holder will be eligible to make a mark-to-market election. You should consult your own tax advisor as to the specific tax consequences to you in the event we are characterized as a PFIC for the taxable year ending December 31, 2014.

The financial reporting obligations of being a public company require significant company resources and management attention.

We are subject to the public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, and the listing requirements of the NASDAQ Global Market, or the NASDAQ. As a result, we have incurred, and will continue to incur, significant legal, accounting and other expenses that we did not incur as a private company, particularly after we are no longer an "emerging growth company" as defined in the JOBS Act. Further, the need to establish the corporate infrastructure demanded of a public company may divert management's attention from implementing our growth strategy. We have made, and will continue to make, changes to our corporate governance standards, disclosure controls and financial reporting and accounting systems to meet our reporting obligations. Any changes that we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all, which could subject us to delisting of our common shares, fines, sanctions and other regulatory action and potentially civil litigation. In addition, we incur significant legal, accounting, reporting and other expenses in order to maintain a listing on the NASDAQ. These expenses relate to, among other things, the obligation to present financial information according to U.S. GAAP in the United States. We are also required to comply with certain disclosure and filing requirements under applicable securities laws in Canada as a reporting issuer in certain provinces.

The price of our common shares is likely to be highly volatile, and you could lose all or part of your investment.

Prior to our recently completed IPO, there was no public market for our common shares in the United States. The trading price of our common shares is likely to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the other risk factors discussed in this section, these factors include:

- the commencement, enrollment or results of our ongoing and planned Phase 3 clinical trials of PRX302 or any future clinical trials we may conduct, or changes in the development status of PRX302;
- any adverse development or perceived adverse development with respect to the FDA's review of our plan for our two Phase 3 clinical trials, or delay in our submission of a BLA to the FDA for PRX302;
- unanticipated serious safety concerns related to the use of PRX302;
- adverse regulatory decisions, including failure to receive regulatory approval for PRX302;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

Table Of Contents

- our ability to obtain resources for us and our clinical trial programs on our desired schedule;
- inability to obtain adequate commercial supply for any approved product or inability to do so at acceptable prices;
- developments concerning our commercial partners, including but not limited to, those with manufacturers;
- competition from existing technologies and products or new technologies and products that may emerge;
- announcements of significant acquisitions, strategic partnerships, joint ventures, new products, capital commitments or other events by us or our competitors;
- the inability to establish collaborations or termination of a collaboration;
- actual or anticipated variations in our quarterly operating results;
- failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- our cash position;
- announcement or expectation of additional financing efforts;
- issuances of debt or equity securities;
- our inability to successfully enter new markets or develop additional product candidates;
- actual or anticipated fluctuations in our competitors' operating results or changes in their growth rate;
- sales of our common shares by us, or our shareholders in the future;
- trading volume of our common shares on the NASDAQ and price;
- market conditions in our industry;
- overall performance of the equity markets and general political and economic conditions;
- introduction of new products or services by us or our competitors;
- additions or departures of key management, scientific or other personnel;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities or industry analysts;
- changes in the market valuation of similar companies;
-

- disputes or other developments related to intellectual property and other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies and product candidates;
- changes in laws or regulations and policies applicable to product candidates, including but not limited to clinical trial requirements for approvals;
- changes in accounting practices;
- significant lawsuits, including patent or shareholder litigation; and
- other events or factors, many of which are beyond our control.

Furthermore, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of our common shares.

Sales of a substantial number of our common shares in the public market by our existing shareholders could cause our share price to fall.

Sales of a substantial number of our common shares in the public market or the perception that these sales might occur, could depress the market price of our common shares and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common shares.

Certain holders of our common shares are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these shareholders could have a material adverse effect on the trading price of our common shares.

Future sales and issuances of our common shares or rights to purchase common shares by us, including pursuant to our equity incentive plan, could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To the extent we raise additional capital by issuing equity or convertible securities, our shareholders may experience substantial dilution. We may sell common shares, convertible securities or other equity securities in

one or more transactions at prices and in a manner we determine from time to time. If we sell common shares, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders.

Table Of Contents

Pursuant to our equity incentive plan, our management is authorized to grant options to our employees, directors and consultants. The number of shares available for future grant under our plan is equal to 10% of all shares of our issued and outstanding common shares at any time. Currently, the number of shares available for issuance under our equity incentive plan each year automatically increases when we issue additional common shares. If our board of directors elects to grant additional options each year our shareholders may experience additional dilution, which could cause our share price to fall.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biochemical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We do not intend to pay dividends on our common shares so any returns will be limited to the value of our shares.

We have never declared or paid any cash dividend on our common shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. The Oxford Loan also contains a negative covenant which prohibits us from paying dividends without the prior written consent of Oxford. Any return to shareholders will therefore be limited to the increase, if any, of our share price.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common shares less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common shares held by non-affiliates exceeds $700 million as of any June 30 before that time or if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth

company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

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

Our charter documents, certain related party contracts and certain Canadian legislation could delay or deter a change of control, limit attempts by our shareholders to replace or remove our current management and limit the market price of our common shares.

Our authorized preferred shares are available for issuance from time to time at the discretion of our board of directors, without shareholder approval. Our articles grant our board of directors the authority, subject to the BCBCA, to determine the special rights and restrictions granted to or imposed on any unissued series of preferred shares, and those rights may be superior to those of our common shares.

Table Of Contents

In addition, provisions in the BCBCA and in our articles, may have the effect of delaying or preventing changes in our management, including provisions that:

- prohibit cumulative voting in the election of directors; and
- require the approval of our board of directors or the holders of a supermajority of our outstanding share capital to amend our articles and our notice of articles.

These provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management. Any of the foregoing could prevent or delay a change of control and may deprive or limit strategic opportunities to our shareholders to sell their shares.

Risks Related To Being A Canadian Entity

We are governed by the corporate laws in British Columbia, Canada which in some cases have a different effect on shareholders than the corporate laws in Delaware, United States.

The material differences between the BCBCA as compared to the Delaware General Corporation Law, or the DGCL, which may be of most interest to shareholders include the following: (i) for material corporate transactions (such as mergers and amalgamations, other extraordinary corporate transactions, amendments to our articles) the BCBCA generally requires two-thirds majority vote by shareholders, whereas DGCL generally only requires a majority vote of shareholders for similar material corporate transactions; (ii) the quorum for shareholders meetings is not prescribed under the BCBCA and is only two persons representing 5% of the issued shares under our articles, whereas under DGCL, quorum requires a minimum of one-third of the shares entitled to vote to be present and companies' certificates of incorporation frequently require a higher percentage to be present; (iii) under the BCBCA a holder of 5% or more of our common shares can requisition a special meeting at which any matters that can be voted on at our annual meeting can be considered, whereas the DGCL does not give this right; (iv) our articles require two-thirds majority vote by shareholders to pass a resolution for one or more directors to be removed, whereas DGCL only requires the affirmative vote of a majority of the stockholders; however, many public company charters limit removal of directors to a removal for cause; and (v) our articles may be amended by resolution of our directors to alter our authorized share structure, including to (a) consolidate or subdivide any of our shares and (b) create additional classes or series of shares, whereas under DGCL, a majority vote by shareholders is generally required to amend a corporation's certificate of incorporation and a separate class vote may be required to authorize alterations to a corporation's authorized share structure. We cannot predict if investors will find our common shares less attractive because of these material differences. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

Risks Related to Aspire Transaction

The sale of our common shares to Aspire Capital may cause substantial dilution to our existing shareholders and the sale of the shares of common shares acquired by Aspire Capital could cause the price of our common shares to decline.

We are registering for sale the Commitment Shares and Initial Purchase Shares that we have issued and 2,714,764 shares that we may sell to Aspire Capital under the Purchase Agreement. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 30 months from the date of this prospectus. The number of shares ultimately offered for sale by Aspire Capital under this prospectus is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase Agreement. Depending upon market liquidity at the time, sales of our common shares under the Purchase Agreement may cause the trading price of our common shares to decline.

Aspire Capital may ultimately purchase all, some or none of the $15.0 million of common shares that, together with the Commitment Shares, is the subject of this prospectus. Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the Purchase Agreement. Sales by Aspire Capital of shares acquired pursuant to the Purchase Agreement under the registration statement, of which this prospectus is a part, may result in dilution to the interests of other holders of our common shares. The sale of a substantial number of our common shares by Aspire Capital in this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

Table Of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our research and development activities and clinical trials, including our ongoing and planned Phase 3 clinical trials of PRX302;
- our ability to obtain and maintain regulatory approval of PRX302, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations;
- our plans to research, develop and commercialize PRX302;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the market for PRX302, and our ability to serve that market;
- our ability to successfully commercialize PRX302, including our ability to develop sales and marketing capabilities, whether alone or with collaborators;
- the rate and degree of market acceptance of PRX302;

- our ability to obtain and maintain intellectual property protection for our current and any future product candidates and our ability to operate our business without infringing the intellectual property rights of others;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party clinical research organization manufacturer;
- the success of competing therapies that are or become available;
- the loss of key scientific or management personnel;
- our expectations regarding the period during which we will be an emerging growth company under the JOBS Act;
- our plans to evaluate development of PRX302 for prostate cancer; and
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

In some cases, you can identify these statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expects,” “inten “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would,” “continue,” “ongoing” or the negative of those term similar expressions, although not all forward-looking statements contain those words. These forward-looking statements reflect our management’s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section of this prospectus entitled “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended, do not protect any forward-looking statements that we make in connection with this offering.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in

this prospectus by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Table Of Contents

USE OF PROCEEDS

This prospectus relates to our common shares that may be offered and sold from time to time by Aspire Capital. We will not receive any proceeds upon the sale of shares by Aspire Capital. However, we may receive proceeds up to $15.0 million under the Purchase Agreement with Aspire Capital. The proceeds received from the sale of the shares under the Purchase Agreement will be used for working capital and general corporate purposes. This anticipated use of net proceeds from the sale of our common shares to Aspire Capital under the Purchase Agreement represents our intentions based upon our current plans and business conditions.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital shares. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common shares for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant. In addition, the terms of our existing debt facility prohibit us from paying dividends without the prior written consent of Oxford.

Table Of Contents

SELECTED CONSOLIDATED FINANCIAL DATA

The following selected financial data should be read together with our financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" incorporated by reference herein. The selected financial data in this section are not intended to replace our financial statements and the related notes. Our historical results are not necessarily indicative of our future results.

The selected consolidated statement of operations data for the years ended December 31, 2013, 2012 and 2011 and the selected consolidated balance sheet data as of December 31, 2013, 2012 and 2011 are derived from our audited financial statements incorporated by reference in this prospectus. The selected statement of operations data for the three months ended March 31, 2014 and 2013 and the selected balance sheet data as of March 31, 2014 are derived from our unaudited financial statements incorporated by reference in this prospectus. The unaudited financial statements have been prepared on a basis consistent with our audited financial statements included in this prospectus and include, in our opinion, all adjustments, consisting of normal recurring adjustments necessary for the fair presentation of the financial information in those statements.

Consolidated Statement of Operations Data (in thousands, except per share data):

	December 31,			March 31,	
	2013	2012	2011	2014	2013
Revenues	$5,000	$—	$—	$—	$5,000
Operating expenses:					
Research and development	10,279	13,523	8,660	6,830	2,871
General and administrative	4,511	5,685	4,635	1,451	1,246
Total operating expenses	14,790	19,208	13,295	8,281	4,117
(Loss) income from operations	(9,790)	(19,208)	(13,295)	(8,281)	883
Other income (expense):					
Interest expense	(1,308)	(1,880)	(895)	(208)	(399)
Interest income	—	—	—	17	—
Gain on revaluation of warrant liability	689	—	—	29	—
Other income (expense), net	(240)	(106)	(11)	(17)	(101)
Total other income (expense)	(859)	(1,986)	(906)	(179)	(500)
Net loss (income) before income tax expense	(10,649)	(21,194)	(14,201)	(8,460)	383
Income tax expense	(500)	—	—	—	(500)
Net loss	$(11,149)	$(21,194)	$(14,201)	$(8,460)	$(117)

Basic and diluted net loss per common share[1] [2]	$(1.39)	$(6.94)	$(6.05)	$(0.52)	$(0.04)
Weighted average shares used to calculate net loss per common share [1] [2]	8,029	3,054	2,345	16,150	3,150

(1) See Note 3 of our Notes to the Consolidated Financial Statements, incorporated herein by reference for an explanation of the method used to calculate the basic and diluted net loss per common share and the number of shares used in the computation of the per share amounts.

(2) Reflects the 52-for-1 share consolidation of our common shares.

Table Of Contents

Consolidated Balance Sheet Data:

	December 31,			March 31,
	2013	2012	2011	2014
Cash, cash equivalents and securities available-for-sale	$48,149	$9,721	$23,410	$40,276
Working capital	41,267	815	17,944	33,412
Total assets	51,892	11,529	24,800	44,285
Promissory notes, including current portion	6,877	12,021	14,702	5,284
Warrant liability	883	—	—	20
Stock-based compensation liability	202	—	—	181
Accumulated deficit	(84,847)	(73,698)	(52,504)	(93,306)
Total shareholders' equity	40,279	(5,105)	6,997	33,285

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

Please see Item 2 in our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2014, filed with the Securities and Exchange Commission on May 13, 2014, and Item 7 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed with the Securities and Exchange Commission on March 14, 2014, which are incorporated herein by reference, for a discussion of our financial condition and results of operations.

Table Of Contents

BUSINESS

We are a clinical-stage biopharmaceutical company focused on developing innovative products for the treatment of urological diseases. We are headquartered in San Diego, California and our common shares currently trade on the NASDAQ Global Market, or NASDAQ. Effective November 13, 2013, we voluntarily delisted from the Toronto Stock Exchange, or TSX. Subsequent to November 13, 2013, our securities are being actively traded on only the NASDAQ. We are currently developing PRX302 as a treatment for the symptoms of benign prostatic hyperplasia, or BPH, commonly referred to as an enlarged prostate. Initially, most men with BPH will be treated with oral medications but many will discontinue drug therapy due to inadequate response and/or side effects, which include sexual dysfunction and cardiovascular side effects. They may then undergo a surgical procedure, which can be painful and have potential long-term sexual side effects, or may stop treatment altogether. PRX302 is designed to be a convenient treatment that is safer and less invasive than surgery and more effective and better tolerated than currently approved pharmaceutical therapies. In our Phase 2b clinical trial, we saw significant symptom relief from a single treatment of PRX302 that was sustained throughout the follow-up period of 12 months, and there were no drug-related erectile dysfunction or cardiovascular side effects reported. In 2009, we licensed exclusive rights to PRX302 from UVIC Industry Partnerships Inc., or UVIC, and The Johns Hopkins University, or Johns Hopkins, for the treatment of the symptoms of BPH. In April 2010, we entered into an exclusive license agreement with Kissei Pharmaceuticals Co., Ltd., or Kissei, pursuant to which we granted Kissei the right to develop and commercialize PRX302 in Japan for the treatment of the symptoms of BPH, prostate cancer, prostatitis or other diseases of the prostate.

PRX302 (generic name: topsalysin), a genetically modified recombinant protein, is delivered via ultrasound-guided injection directly into the prostate. This membrane-disrupting protein is selectively activated by an enzyme in the prostate, leading to localized cell death and tissue disruption without damage to neighboring tissue and nerves. This method of administration limits the circulation of the drug in the body, and we believe that this limited systemic exposure to the drug, together with how the drug is activated in the body, greatly diminishes the risk of side effects. In our randomized, double-blind, placebo-controlled Phase 2b clinical trial, PRX302 produced clinically meaningful and significant improvement in both subjective and objective measures of BPH symptoms, including the International Prostate Symptom Score, or IPSS, outcome measure.

In October 2013 we initiated the first of two planned Phase 3 clinical trials of PRX302 for the treatment of the symptoms of BPH. Based on feedback from our guidance meeting with the FDA in February 2013, we expect to enroll approximately 440 patients in this Phase 3 clinical trial. This Phase 3 clinical trial will use the IPSS outcome measure evaluated over 12 months as the primary endpoint, which is consistent with clinical trials of another injectable currently under development by a third party for the treatment of the symptoms of BPH. Assuming sufficient capital resources, we plan to commence our second Phase 3 clinical trial following an administrative analysis by an independent data monitoring committee conducted once all patients have completed three months in the first Phase 3 clinical trial, which analysis we expect to occur by the end of 2014. The company and its representatives will remain blinded to the results of this administrative analysis throughout the duration of the study until after the database is locked at the conclusion of the 12 month study.

In the second half of 2014 we expect to initiate a proof of concept study of PRX302 for the treatment of localized prostate cancer. PRX302 has been engineered to be activated by enzymatically active prostate specific antigen (PSA), which is found in the transition zone of the prostate as well as in prostate cancer cells. The highly targeted mechanism by which PRX302 selectively destroys prostate tissue in BPH also makes PRX302 a promising treatment approach for localized prostate cancer.

On August 16, 2013, we commenced our U.S initial public offering and listing on the NASDAQ pursuant to a Registration Statement on Form S-1 (File No. 333-186724) that was declared effective by the Securities and Exchange Commission on August 16, 2013 and that registered our common shares with a maximum aggregate offering price of $74.8 million. On August 23, 2013, we sold 13,000,000 of our common shares to the public at a price of $5.00 per share for an aggregate gross offering price of $65 million.

PRX302 - Mechanism of Action

PRX302 is a genetically altered form of the naturally occurring protein proaerolysin. In nature, proaerolysin is produced by *Aeromonas* bacteria, which are commonly found as a contaminant in fresh water and fresh water fish. We have altered the sequence encoding the bacterial protein so that PRX302 is only activated by active prostate specific antigen, or PSA (as shown in the figure below), an enzyme that is produced in large quantities in the prostate of men with BPH.

Table Of Contents

PRX302 binds to the GPI-anchored receptors on the cell surface of prostate cells. Once activated by PSA, PRX302 combines with other activated PRX302 molecules, forming stable transmembrane pores that induce cell death. We believe this targeted prostate cell ablation will lead to relief of LUTS in patients with BPH. In addition, PRX302 has not been detected in plasma following injection into the prostate. The prostate specific activation of PRX302 by enzymatically active PSA thus limits exposure of non-prostate tissues to the drug's activity, contributing to the safety of the therapy.

The mechanism of action is shown in the figure below.

PRX302 Mechanism of Action

Background on BPH

BPH is a non-cancerous enlargement of the prostate gland that commonly affects men who are age 50 and older. BPH causes a restriction in urine flow from the urethra resulting in lower urinary tract symptoms, or LUTS. BPH, and its associated clinical manifestations of LUTS, is one of the most common medical conditions of aging men in the United States, with approximately 70% of men aged 60-69 years and 80% of men older than the age of 70 being affected by BPH. The number of men with symptoms of BPH is expected to increase as the male population ages. Our market research suggests that as many as 36 million men in the United States are affected by BPH with approximately 5 million of these men suffering from bothersome symptoms. Symptomatic BPH greatly diminishes a patient's quality of life. It causes a significant array of LUTS, including increased urinary frequency, urgency to urinate, frequent night-time urination, weak urine stream, and incomplete emptying of the bladder. In addition, men with BPH symptoms are predisposed to a higher risk of urinary tract infections, urinary stone formation, bladder damage, and in very late stage and/or unattended cases, renal damage.

Table Of Contents

Current Therapies for BPH

Physicians and patients choose treatments for the symptoms of BPH primarily based on the severity of symptoms, the patient's quality of life and the presence of other medical conditions. Treatment options include watchful waiting, lifestyle changes, oral medications, minimally invasive surgical therapies, or MIST, or more aggressive surgical therapies, such as transurethral resection of the prostate, or TURP, or open prostatectomy. Our market research indicates that approximately 3 million men in the United States are taking oral drug therapy and there were approximately 200,000 surgical procedures for the treatment of the symptoms of BPH conducted in 2011.

The effectiveness of treatments for the symptoms of BPH is measured by IPSS and improvement in peak urine flow rate, or Qmax. IPSS is a patient recorded, composite assessment that takes into account factors such as ability to empty the bladder, frequency of urination, intermittency of urination, urgency of urination, weak strength of urine stream, straining while urinating, and having to urinate at night after going to bed. This index is measured on a 0 to 35 scale with 0 being defined as having no problems and 35 defined as the high end of severe symptoms. Patients are typically considered to have mild symptoms with IPSS of 1 to 7, moderate symptoms with scores of 8 to 19 and severe symptoms with scores of 20 to 35. An improvement of 3 points in IPSS is generally considered clinically meaningful by urologists. IPSS is a validated primary clinical endpoint used to assess the treatment benefit in BPH clinical trials and has served as the primary efficacy endpoint for the approval of many products for the treatment of the symptoms of BPH. A difference of at least a 2 point improvement in IPSS between active and control is generally required for FDA approval.

Oral Drug Therapy

The most common form of therapy for men experiencing mild to moderate LUTS associated with BPH is oral drug therapy. Current classes of oral medications available for treatment of the symptoms of BPH include a-blockers, 5-a-reductase inhibitors, or 5-aRIs, a combination of an a-blocker and 5-aRI, and a phosphodiesterase Type 5 inhibitor, or PDE5. An a-blocker provides rapid relief of BPH symptoms, but does not prevent continued growth of the prostate. Examples of a-blockers include terazosin, doxazosin, tamsulosin, alfuzosin, and silodosin. Frequently reported side effects of a-blockers include hypotension, or low blood pressure, dizziness and feeling of weakness. 5-aRIs, such as finasteride and dutasteride, reduce the size of the prostate and thus provide symptom relief. It may take up to six months from starting treatment with 5-aRI for the prostate to reduce in size and for patients to experience the benefit of treatment. Side effects include sexual dysfunction. In addition, tadalafil (marketed by Eli Lilly as Cialis®), a PDE5 inhibitor (a class of drugs typically prescribed for erectile dysfunction), was shown to improve IPSS after four weeks of dosing and has been approved for treatment of the symptoms of BPH. Headache and dyspepsia, or indigestion, are the most commonly observed side effects of Cialis®, which is not recommended for use in combination with an a-blocker because of the risk of hypotension.

Many men will discontinue oral drug therapy due to inadequate response and/or the above side effects. Another drawback of the currently available oral therapies is the necessity of taking one or more pills daily. Published patient survey data (N=2,166) suggests that as many as 57% of patients taking oral drug therapy discontinue use within the first three years.

In previously completed clinical trials, each of these classes of oral medications has typically produced approximately 3 to 6 point reductions in IPSS, but the actual magnitude of treatment benefit observed compared to placebo is generally two to three points.

Minimally Invasive Surgical Therapies

Minimally invasive surgical therapies used to treat the symptoms of BPH include transurethral microwave thermotherapy, or TUMT, transurethral needle ablation, or TUNA, Urolift® and green laser treatment, which delivers high energy to ablate the prostatic tissue as an alternative to TURP. These treatments, frequently referred to as MIST, are generally less effective than surgical procedures in reducing the size of the prostate gland and often require retreatment within three years. However, these treatments may require catheterization and are still associated with pain and the potential for complications such as bleeding and long-lasting side effects such as urinary incontinence and sexual dysfunction, including erectile dysfunction and retrograde ejaculation (semen flowing backward into the bladder). Studies of MIST procedures have shown varying improvements in IPSS, with TUNA and TUMT showing improvement in IPSS of approximately 10 to 13 points.

Table Of Contents

Other Surgical Options

Surgical procedures such as TURP typically reduce the size of the prostate gland and relieve the pressure on the urethra by ablating the prostate tissue that blocks the flow of urine. Studies of surgical procedures have generally shown reductions in IPSS of approximately 16 points. TURP is performed under spinal or general anesthesia, which carries the risk of side effects. TURP may result in nerve damage, bleeding (sometimes requiring transfusion), and long-lasting side effects, such as urinary incontinence and sexual dysfunction, including erectile dysfunction and retrograde ejaculation.

PRX302 for the Treatment of the Symptoms of BPH

Overview

PRX302 is designed to be a safe, simple and convenient treatment that provides rapid and sustained relief of BPH symptoms. It is delivered through a targeted injection into the prostate, precisely ablating the prostate tissue without damaging neighboring tissue and nerves. This method of administration limits the circulation of the drug in the body and we believe that this limited systemic exposure to the drug, together with how the drug is activated in the body, greatly diminishes the risk of side effects. In our Phase 2b clinical trial, PRX302 has been shown to significantly improve symptoms of BPH through 12 months of follow-up after a single treatment.

The injection of PRX302 is individualized to each patient based on the size of his prostate and the drug is delivered in a procedure that can be performed in a urologist’s office. The entire process can be completed during a short office visit, and the actual injection of the drug into each of the two lobes of the prostate takes approximately three minutes. A physician administering PRX302 may elect to administer a local anesthetic before injection. Most urologists are familiar with the transrectal route of administration, as it is the same method urologists use to take biopsies of the prostate.

PRX302 Transrectal Administration Schematic

Market research we conducted with 100 urologists has shown that PRX302 compares favorably to both oral therapies and procedures on a number of key attributes related to effectiveness, safety, tolerability, and burden placed on the patient. Specifically, when shown results from our Phase 2b clinical trial, the physicians viewed PRX302 as being more effective and having a better side effect profile than currently available oral drugs. Administration of PRX302 was also perceived as more effective, safer, and easier to perform than MIST procedures, TUNA and TUMT. When compared to TURP surgery, PRX302 was also perceived as safer and easier to administer. In this market research, physicians indicated a willingness to consider PRX302 as an alternative to both oral therapies and surgical procedures and also viewed PRX302 as a potential new choice for men who have discontinued oral therapy and are not willing to undergo a surgical procedure.

Clinical Overview

To date, we have completed six clinical trials of PRX302 and we are currently enrolling patients in our first Phase 3 clinical trial for PRX302. Four completed clinical trials were for the treatment of the symptoms of BPH and two were for the treatment of prostate cancer. Prior to the initiation of our Phase 3 clinical trial of PRX302 for the treatment of the symptoms of BPH, a total of 126 patients with moderate to severe BPH symptoms and 30 patients with prostate cancer have been treated with PRX302, for a combined PRX302 exposure of 156 patients. In each of the six trials, patients were monitored for 12 months following a single treatment of PRX302.

Table Of Contents

We conducted five clinical trials using the transperineal route for the intraprostatic injection of PRX302. In the most recent clinical trial we used the transrectal route for intraprostatic injection, the route commonly used for biopsies of the prostate. The transrectal route appears to be as well-tolerated as the transperineal route and is more familiar to urologists.

Clinical trials of PRX302 for the treatment of the symptoms of BPH completed to date have consistently shown clinically meaningful, sustained efficacy with regard to improvement in LUTS, as measured by IPSS and Qmax, the standard measures of the treatment of symptoms for BPH. PRX302 has been well-tolerated in all completed clinical studies to date. Adverse events in our completed clinical trials were typically mild and transient in nature, limited to local discomfort and irritative urinary symptoms that generally occurred on the same day as study drug injection. There were no drug-related erectile dysfunction or cardiovascular side effects reported.

Based on results from our completed clinical trials, we plan to conduct two multicenter, double-blinded Phase 3 clinical trials to confirm the safety and efficacy of PRX302 injection via the transrectal route for the treatment of moderate to severe BPH symptoms, the first of which was initiated in October 2013. We believe these studies will support obtaining marketing approval of PRX302 in the United States, Europe, and other territories for the treatment of the symptoms of BPH.

Clinical Development in BPH

Our clinical program for PRX302 is summarized below.

Completed Clinical Development

CLINICAL TRIAL	**STATUS**	**TRIAL DESIGN**
PRX302-2-03	Completed	Randomized, double-blinded, placebo-controlled trial of a single transperineal intraprostatic treatment of PRX302
TRIUMPH		
Phase 2b		92 patients; 61 on PRX302; 31 on placebo
		Dosing: 0.6 µg/g

		Volume: 20% of prostate volume Randomized dose-escalation, multicenter trial of a single transrectal intraprostatic treatment of PRX302
PRX302-2-06		
Transrectal Study Phase 1/2	Completed	40 patients; 32 on PRX302 in 4 dosing cohorts; 8 on placebo Dosing: 0.15µg/g, 0.30µg/g, 0.60µg/g, 1.2µg/g Volume: 20% of prostate volume Open-label, safety, volume escalation clinical trial of a single transperineal intraprostatic treatment of PRX302
PRX302-2-02 Phase 2a	Completed	18 patients Dosing: 0.3µg/g, 0.6µg/g, 0.9µg/g Volume: 10 to 30% of prostate volume Open-label, safety, dose-escalation clinical trial of a single transperineal intraprostatic treatment of PRX302
PRX302-2-01 Phase 1	Completed	15 patients Dosing: 0.025µg/g, 0.072µg/g, 0.25µg/g, 0.35µg/g Volume: 1.5 to 2.0 mL

Table Of Contents

Ongoing and Planned Clinical Development

CLINICAL TRIAL	STATUS	TRIAL DESIGN
		Prospective, randomized, double-blind, placebo-controlled clinical trial of a single transrectal intraprostatic treatment of PRX302, which will utilize the IPSS outcome measure evaluated at 12 months as the primary endpoint
PLUS-1		
Phase 3 Trial #1	Enrolling	440 patients Dosing: 0.6µg/g Volume: 20% of prostate volume
Phase 3 Trial #2	Planned but not initiated	Prospective, randomized, double-blind, placebo-controlled clinical trial of a single transrectal intraprostatic treatment of PRX302 Dosing: TBD Volume: 20% of prostate volume Safety of repeat dose and long-term safety of transrectal intraprostatic treatment of PRX302
Open-Label Safety Study Phase 3	Planned but not initiated	Approximately 100 patients Dosing: TBD Volume: 20% of prostate volume

PLUS-1 Randomized, Double-Blind, Placebo-Controlled Transrectal Route of Injection Clinical Trial

In October 2013, we initiated the first of two Phase 3 clinical trials of PRX302 for treatment of the symptoms of BPH, which trial we sometimes refer to as PLUS-1. Based on feedback from our guidance meeting with the FDA in February 2013, we have decided to enroll approximately 440 patients in this Phase 3 clinical trial. This first Phase 3 clinical trial will be a randomized, double-blind, dose confirmation, multicenter, vehicle-controlled clinical trial to confirm the efficacy and safety of a single treatment of PRX302 transrectally administered in patients with moderate

to severe LUTS due to BPH. This multicenter, multinational clinical trial will randomize patients across as many as 100 clinical trial sites to one of two treatment groups. The primary outcome measure is the change from baseline in IPSS, which is the outcome measure that has been used in previous clinical trials of PRX302 and for the regulatory approval of oral medications for treatment of the symptoms of BPH as well as MIST procedures. This change from baseline will be evaluated over 12 months, which time frame is consistent with clinical trials of another injectable currently under development for the treatment of the symptoms of BPH. Secondary outcome measures will include an improvement in Qmax. In this first Phase 3 clinical trial, we intend to have an independent data monitoring committee conduct an administrative analysis once all patients have completed three months of treatment to assess safety and treatment effect. The Company and its representatives will remain blinded to the results of this administrative analysis throughout the duration of the study until after the database is locked at the conclusion of the 12 month study. Assuming sufficient capital resources, we plan to commence our second Phase 3 clinical trial following administrative analysis, which we expect to occur by the end of 2014.

TRIUMPH Phase 2b Randomized, Double-Blind, Placebo-Controlled Clinical Trial

In 2010, we completed TRIUMPH, a multicenter, randomized, double-blinded, placebo-controlled Phase 2b clinical trial of PRX302 in 92 patients with moderate to severe BPH symptoms. The primary objective of this clinical trial was to evaluate the effect on symptoms of BPH of PRX302 versus placebo. Patients randomized to placebo, which is otherwise referred to as the vehicle, were administered by injection an equivalent volume of phosphate-buffered saline that did not include active drug product. The patient population that we used to evaluate efficacy in this clinical trial, as defined by the clinical trial protocol, was the efficacy evaluable, or EE, population of patients, which was defined as those 73 patients who (1) received the full treatment, (2) completed three month assessments, and (3) had no major protocol violation, as determined by a blinded, independent review panel of urology experts. The intent-to-treat, or ITT, and safety patient populations consisted of all 92 patients who received any study drug. Our efficacy analyses in this clinical trial used the last observation carried forward, or LOCF, method to impute missing post-baseline data.

The results of this clinical trial were:

- *PRX302 improved LUTS due to BPH* – We achieved the primary endpoint of this clinical trial, which was a statistically significant improvement in IPSS at three months following injection for patients treated with PRX302 versus patients who received vehicle. PRX302 treatment resulted in a 9.1 average reduction of IPSS, as compared to a 5.8 average reduction in patients who received vehicle (p=0.040).

- *Improvement was clinically meaningful, rapid and sustained* – Improvement in IPSS was observed as early as 14 days following injection and was sustained through the twelfth month of observation. This improvement in IPSS was clinically meaningful, and superior to vehicle.

Table Of Contents

- *Improvement in Qmax* – PRX302 treatment resulted in an approximately 3.1 mL/sec average increase in Qmax at three months, as compared to 1.3 mL/sec for vehicle (p=0.047). The improvement in Qmax for PRX302 was apparent from the first post-baseline assessment and sustained through the twelfth month of observation.

- *PRX302 was well-tolerated* – The PRX302 injection was well-tolerated by patients in this clinical trial. The most common adverse events that were potentially attributable to PRX302 are set forth in the table below. These adverse events generally are not unexpected manifestations of the intraprostatic cellular destruction and inflammation integral to the PRX302 mechanism of action. The median duration for each of these adverse events was typically less than two days. In general, these adverse events were mild and transient, began within the first few days after treatment (primarily on the same day as the study drug injection) and were resolved without further complications.

There were no drug-related erectile dysfunction or cardiovascular side effects reported in this clinical trial. In addition, 16.1% of patients in the vehicle group dropped out of the study due to lack of efficacy and the need for alternative therapy as compared to 3.3% of patients in the active group.

Adverse Events Occurring in ≥5% of Subjects treated with PRX302 (ITT Population)

Adverse Event[1]	**Vehicle (N=31)** **n (%)**	**PRX302 (N=61)** **n (%)**
Hematuria, or presence of red blood cells in urine	11(35.5)	18(29.5)
Dysuria, or painful urination	2(6.5)	17(27.9)
Pollakiuria, or increased frequency of urination	5(16.1)	14(23.0)
Micturition Urgency, or urgency of urination	3(9.7)	13(21.3)
Perineal Pain	0(0.0)	7(11.5)
Vertigo	2(6.5)	4(6.6)
Malaise	0(0.0)	4(6.6)

(1) MedDRA Dictionary-coded preferred terms.

In summary, these results demonstrate that PRX302 is able to maintain a treatment benefit based on both measures of efficacy, IPSS and Qmax, which is clinically meaningful and sustained for the 12 months of monitoring in this clinical trial.

IPSS and Qmax in the Phase 2b BPH TRIUMPH Clinical Trial

N=73 Efficacy-Evaluable Patients using LOCF; 52 PRX302 and 21 Vehicle

Table Of Contents

In our studies and other intraprostatic injection studies, vehicle response rates of 5 to 7 point improvements in IPSS have been observed. We believe that the vehicle response is due in part to the fluid injection potentially ablating prostate cells.

Although the clinical trial protocol did not specify an ITT population analysis, an improvement of 8.2 points in IPSS was observed in the active group of the ITT population. This was not statistically significant when compared to an improvement in the vehicle group of 7.2 points. Thirteen percent of the active group and 23% of the vehicle group were included in the ITT population but not included in the EE population because they were deemed major protocol violators based on confounding factors. Examples of confounding factors were taking prohibited medications, including other medications to treat the symptoms of BPH, or undergoing prohibited procedures during the clinical trial.

Transrectal Phase 1/2, Randomized, Double-Blind, Placebo-Controlled Clinical Trial in BPH

In March 2012, we completed dosing in a multicenter, randomized, double-blinded, vehicle-controlled Phase 1/2 clinical trial of PRX302 using the transrectal route of administration for the intraprostatic injection of PRX302. Each of the previous clinical trials used transrectal ultrasound to guide the intraprostatic injection, but this clinical trial was the first to use the rectum as the route of administration rather than passing the needle through the perineum. The transrectal route has the advantage of being very similar to the routine prostate biopsy procedure, and therefore requires little extra training for the practicing urologist. The primary endpoint of this clinical trial was to evaluate the three-month safety and tolerability of escalating doses of PRX302. The safety data from this new route of administration of PRX302 were needed for a comparison with the safety profile obtained from our previously-conducted Phase 1 and 2 clinical trials, which utilized a transperineal route of administration.

We enrolled 40 patients with moderate to severe BPH symptoms in this clinical trial who were randomized to PRX302 or placebo in a 4:1 ratio within each of the four escalating dose cohorts. All patients in this clinical trial received a single, transrectal, intraprostatic treatment of study drug or vehicle at 20% of the patient's prostate volume, in four sequential cohorts according to escalating PRX302 dose: 0.15, 0.30, 0.60, and 1.20 μg/g prostate. Dose escalation decisions were guided by an independent data monitoring committee for each new cohort after all patients in the previous cohort had been followed for at least 15 days after study drug administration.

The results of this clinical trial showed that PRX302 was generally well-tolerated. The side effect profile in this transrectal clinical trial was consistent with the side effects reported in the previous, transperineal PRX302 clinical trials, indicating that PRX302 injection by the transrectal route was tolerated at least as well as the transperineal route. There was one serious adverse event that was deemed by the investigator to be related to injection of PRX302 in this clinical trial. This serious adverse event of urinary retention required an indwelling catheter followed by TUNA. There were no reports of sepsis in this clinical trial. With the switch to a transrectal route of administration, there is a

potential risk of sepsis as currently the rate of sepsis with prostate biopsies in the United States is approximately 3-5%. However, prostate biopsies involve as many as 20 punctures and a large needle, whereas PRX302 administration requires only two punctures with a smaller needle. There were no drug-related erectile dysfunction or cardiovascular side effects reported in this clinical trial.

The small sample size of only eight patients on PRX302 and two patients on vehicle in each cohort was insufficient to show statistically significant improvements in BPH symptoms compared to vehicle. Although improvement in IPSS was noted on average for all dose cohorts through 12 months, there is no meaningful difference between PRX302 and vehicle-treated patients. We do not believe that any conclusions about efficacy can be drawn from this study due to the small sample size.

In our TRIUMPH clinical trial, we observed post-injection transient elevations of two markers: PSA, a marker of prostate tissue disruption, and serum C-reactive protein, or CRP, a non-specific marker of associated inflammation. Post-injection transient elevations in PSA and CRP were also observed in the transrectal study, suggesting that the targeted delivery of PRX302 to the prostrate is successfully achieved with either the transperineal or the transrectal route of administration.

Phase 2a Open-Label Clinical Trial in BPH (PRX302-2-02)

In 2009, we completed an open-label, multicenter, Phase 2a clinical trial in BPH to evaluate the safety and tolerability of PRX302. We enrolled 18 patients with moderate to severe BPH symptoms who were either unresponsive to, intolerant to or unwilling to use oral medications for treatment of the symptoms of BPH. In this clinical trial, three cohorts of six patients each received a single treatment of PRX302 administered via transperineal injection. We measured therapeutic activity through changes in IPSS, Qmax, and quality of life scores compared to baseline scores at screening. In addition, we monitored changes in prostate volume. In this clinical trial, PRX302 was well-tolerated and patients attained meaningful symptomatic relief through follow up of 12 months following a single treatment. Based on the results of this clinical trial, we identified 20% of total prostate volume as our volume dose for our Phase 2b clinical trial.

Table Of Contents

Phase 1 Open-Label Clinical Trial in BPH (PRX302-2-01)

In 2008, we completed an open-label, multicenter, Phase 1 clinical trial in BPH to evaluate the dose of PRX302 needed to demonstrate therapeutic activity following a single treatment, as well as to evaluate safety and tolerability. We enrolled 15 patients with moderate to severe BPH symptoms who were either unresponsive to, intolerant to or unwilling to use oral medications for treatment of the symptoms of BPH. We administered PRX302 to five cohorts of three patients each at escalating doses of PRX302. PRX302 was well-tolerated.

Plans For Future Clinical Development

To date, no patients have been administered more than one treatment of PRX302. Assuming sufficient capital resources, we are planning to initiate an open label repeat dose clinical trial before the end of 2015, in which patients from our transrectal clinical trial, as well as patients from our first Phase 3 clinical trial, will be eligible to receive a repeat dose of PRX302, at least 12 months after their first dose. We believe this planned repeat dose Phase 3 clinical trial is supported by results from our pre-clinical study of repeat dosing in monkeys. In this pre-clinical study, two treatments of PRX302 were given to monkeys 56 days apart. Data from this study indicated that PRX302 resulted in ablation of cells after both the first and the second dose, even in the presence of circulating antibodies, and did not result in hypersensitivity.

Background on Prostate Cancer

Prostate cancer is a large and complex problem. In 2013, there were 238,590 new cases of prostate cancer and 29,720 deaths caused by prostate cancer in the US alone. It is currently the most common cancer in men and the fourth leading cause of death due to cancer.

Before the advent of an easy test to screen for PSA levels in the blood, prostate cancer would typically present having metastasized to bones and other organs with a poor prognosis for the patient’s survival. Today, with an increased life expectancy and an increased awareness by men of the importance of health screening from as early as 40 years of age and the use of the simple blood test to check PSA levels, many men are now being diagnosed with early stage prostate cancer before it spreads beyond the confines of the prostate not all of which is destined to spread beyond the prostate and become potentially life-threatening.

Once diagnosed with early stage localized disease within the prostate, a patient is typically faced with a difficult decision of choosing between two extreme treatment options or choosing active surveillance. The patient can choose to treat the cancer either by removing the whole gland in the form of a prostatectomy or by undergoing radiation treatment of the whole gland. While these treatments offer a good chance of cure, they are often associated with considerable morbidity, including incontinence, erectile dysfunction and rectal toxicity. An alternative to radical treatment for many patients is active surveillance, an increasingly popular method of monitoring prostate cancer that does not offer any therapeutic benefit but does provide additional information which can be used to make an informed decision as to whether treatment is necessary or whether the patient could remain in active surveillance. The additional information is typically in the form of monitoring PSA levels and disease progression from repeat biopsies over time. More recently, an additional assessment can be utilized, multi-parametric MRI, which can aid in visualizing and locating the cancer within the prostate and can be used to guide the subsequent biopsy to confirm grading of the cancer. If there is any sign of cancer changing to a more aggressive form then radical therapy is offered at that time.

The advancement of technology, including the development of the multi-parametric MRI and software to co-register the MRI images with the ultrasound images, enables physicians to more accurately locate the tumors when biopsying the patient. In addition, it also means that there is an opportunity to treat those localized lesions. The focal treatment of early stage prostate cancer is in line with that used for other solid tumors such as breast or liver where the goal is to remove the tumor and preserve as much of the organ as possible.

We believe that these advances in technology will enable physicians to guide an injection of PRX302 directly into a tumor known to be rich in enzymatically active PSA, which is needed for the activation of PRX302. Therefore, we believe that PRX302 could be used to ablate early stage tumors located in the prostate and intend to pursue proof of this concept. To date from completed trials in BPH, 126 patients have been treated with PRX302 and it appears to be safe and well tolerated with no adverse effects on erectile function. Preclinical data have also demonstrated PRX302 activity in treatment of prostate tumors using xenograft animal models.

Clinical Development in Prostate Cancer

Phase 2 Open-Label Clinical Trial in Prostate Cancer

We completed a Phase 2 clinical trial in prostate cancer in September 2009 in six patients with biopsy-proven, locally-recurrent prostate cancer that, following radiation therapy, showed signs of disease progression evidenced by rising levels of PSA. Therapeutic activity in the form of overall decreases in PSA levels and in the number of adenocarcinoma-positive biopsy cores following PRX302 treatment was observed in two of six patients.

Table Of Contents

Phase 1 Open-Label Clinical Trial in Prostate Cancer

In May 2008, we completed a multicenter, open-label, dose-escalation Phase 1 clinical trial of PRX302 in 24 patients in the United States with biopsy-proven, locally-recurrent prostate cancer that, following radiation therapy, showed signs of disease progression evidenced by rising levels of PSA. Elevated and rising levels of PSA can be a sign of the presence or progression of prostate cancer. The primary clinical endpoint of this clinical trial was to examine the safety and tolerability of PRX302 with therapeutic activity as the secondary clinical endpoint. Clinical trial results demonstrated that PRX302 was well-tolerated and showed early signs of therapeutic activity following a single intraprostatic treatment.

No PRX302 treatment-related serious adverse events were reported and the treatment-related adverse effects that were reported were mild and were primarily associated with the injection procedure.

Plans for Future Clinical Development

We are currently developing a protocol for a proof of concept study to evaluate the potential of PRX302 to treat patients with localized, MRI-visible prostate cancer, which we expect will be initiated in the second half of 2014.

Our Strategy

Our business strategy is to develop and commercialize innovative products for the treatment of urological diseases. The elements of our strategy include the following:

- *Complete clinical development of PRX302 for the treatment of the symptoms of BPH*. PRX302 previously achieved its primary efficacy endpoint in a completed Phase 2b clinical trial in patients with moderate to severe BPH symptoms. We intend to conduct two Phase 3 clinical trials based upon guidance from the FDA and European regulatory agencies. We initiated the first such clinical trial in October 2013. If our Phase 3 clinical trials are successful, we plan to submit a biologics license application, or BLA, to the FDA and marketing authorization application, or MAA, to the European Medicines Agency, or EMA.

- *Initiate a clinical trial of PRX302 for the treatment of localized prostate cancer.* We intend to design and initiate a proof of concept study in prostate cancer using PRX302 to treat patients with localized, MRI-visible prostate

tumors.

- *Maximize the commercial potential of PRX302*. If approved, we intend to commercialize PRX302, alone or with a partner, in the United States, and to enter into collaboration arrangements for commercialization in other markets.

- *Opportunistically in-license or acquire additional clinical-stage product candidates or approved products in our area of focus*. We may enhance our product pipeline through strategically in-licensing or acquiring clinical stage product candidates or approved products for urological diseases. We believe that our experience with developing urology therapeutics may make us an attractive partner for companies seeking to out-license products or develop product candidates in this area of focus.

Competition

We expect that PRX302 will compete with the current treatment options for the symptoms of BPH, which include oral drug therapy and surgery. Oral drug therapies include (a) a-blockers, such as tamsulosin (marketed under various trade names by numerous companies, including as Flomax® by Astellas Pharma), alfuzosin (marketed in the United States by Sanofi as Uroxatral®), doxazosin (marketed by Pfizer as Cardura® and CarduraXL®) and silodosin (marketed by Watson Pharmaceuticals as Rapaflo® in the United States), (b) 5-a reductase inhibitors, such as dutasteride (marketed by GlaxoSmithKline plc as Avodart®) and finasteride (marketed by Merck & Co., Inc. as Proscar®), and (c) combinations of a-blockers and 5-a reductase inhibitors such as tamsulosin and dutasteride (marketed by GSK as Jalyn®). In addition, Eli Lilly and Company's oral drug tadalafil (marketed as Cialis®), a PDE5 inhibitor, obtained FDA approval for the treatment of the symptoms of BPH in October 2011. Several MIST procedures are available, including transurethral microwave thermotherapy, or TUMT, TUNA, photo-selective vaporization of prostate, holmium laser enucleation of the prostate, transurethral electro vaporization of the prostate, Urolift, which is designed to open the urethra directly without the need to resect or ablate prostate tissue and interstitial laser coagulation. Currently, the most commonly used MIST procedures are laser ablations of the prostate, TUMT, and TUNA. Surgery for BPH treatment is usually considered in patients who fail drug therapy as a result of side effects or inadequate relief of symptoms, have refractory urinary retention, or have recurrent urinary tract infections. Alternatively, surgery may be the initial treatment in patients with severe urinary symptoms. Surgical procedures for BPH include TURP, as well as other procedures such as transurethral incision of the prostate and transurethral vaporization of the prostate.

Table Of Contents

In addition, there are other treatments that are currently in clinical development for the treatment of the symptoms of BPH. Nymox Pharmaceutical Corporation's injectable NX-1207 is currently in Phase 3 clinical trials for the treatment of the symptoms of BPH. Light Sciences Oncology Inc.'s Aptocine™ is currently in Phase 2 clinical trials for the treatment of the symptoms of BPH.

Sales and Marketing

We do not currently have a sales, marketing or distribution organization. We intend to commercialize PRX302 alone by establishing, either internally or through a contract sales force, a urology sales force to sell PRX302, if approved, in the United States, or through partnership. We plan to partner with third parties to commercialize PRX302 outside the United States.

Specifically, we intend to:

- establish a sales force in the United States of experienced urology and other specialty-care sales representatives;
- build a marketing organization;
- establish commercialization alliances with larger or more specialized pharmaceutical and sales organizations; and
- generate and use pharmacoeconomic data to support the cost savings and therapeutic benefits of PRX302.

Manufacturing

We neither currently possess nor do we plan to develop our own manufacturing capabilities. All of our manufacturing is, and will be, outsourced to third parties with oversight by our internal managers. In 2007, we entered into a manufacturing and supply agreement with Dompé pharma S.P.A., or Dompé, to manufacture batches of PRX302 drug substance. Technology transfer and process scale-up activities were conducted in late 2009 and early 2010 by Dompé, with the manufacture of clinical trial supplies of PRX302 completed during 2010, including the clinical trial supply that we anticipate needing for the first Phase 3 clinical trial. In 2011, we entered into a manufacturing and supply agreement with Boehringer Ingelheim RCV GmbH & Co KG, or BI, to manufacture PRX302. The manufacture of PRX302 drug substance starts with a vial of the working cell bank of *Aeromonas salmonicida* bacteria which is then processed through four consecutive stages involving: batch fermentation and harvest, purification using immobilized

metal affinity chromatography, purification using an ionic exchange chromatography and bulk formulation of PRX302 drug substance. The entire manufacturing process takes approximately two weeks.

There has been a successful transfer of the technology for both the production and release of PRX302 from Dompé to BI and scale-up up to the commercial batch size is underway which we expect to complete by the end of 2014. This full scale commercial batch will be used to supply drug product for the second Phase 3 clinical trial. Although PRX302 is manufactured from readily available materials using standard pharmaceutical methods and equipment, any replacement of BI as our manufacturer may lead to significant delays and increase our costs.

Boehringer Ingelheim RCV GmbH & Co KG

In June 2012, we entered into a technology transfer and supply agreement with BI, for the provision of technology transfer services and for the establishment of certain manufacturing processes for, and the manufacture of, purified PRX302, the diluting agent for use in PRX302 drug products and placebos, and a placebo to be used in clinical trials. We will be required to make payments based upon the provision and completion of certain tasks specified in the agreement. Starting in 2013, the prices of BI's services will be adjusted annually based on the average of the Austrian trade index and the average Standard Wages Index, both as of July of the previous year, subject to certain restrictions. BI will be required to manufacture the products in line with certain project timelines. If we postpone the performance of any services, we may be required to pay certain postponement fees. Additionally, if we cancel any services we will be required to pay the entire cost for such services and the entire cost of any materials that cannot be returned by BI to the appropriate vendor or otherwise used by BI. If we are required to have any product manufactured outside our expected manufacturing cycles due to an unforeseen loss of product, we will have to work with BI to arrange an available manufacturing slot and our receipt of drug product may be delayed. BI must provide all services under the agreement, including the manufacture, packaging, storing and delivery of PRX302 drug products, in accordance with cGMP (as defined below), as specified by the FDA. The agreement has an initial term of six years and will automatically renew for a single five-year period unless either party objects to such renewal at least two-years prior to the expiration of the agreement. Either party may terminate the agreement early for cause, including for any uncured material breach of the agreement, the other party's insolvency or the assignment of the other party's rights or obligations to a direct competitor of the non-assigning party. Additionally, we have the right to terminate the agreement immediately upon the rejection or non-approval of a regulatory filing due to medical, safety or regulatory concerns or in the event that we abandon our clinical program for PRX302 due to any clinical failure, subject in each case to payment of specified termination costs to BI.

Table Of Contents

Intellectual Property

We hold commercial rights to PRX302 in major markets, including, Canada, the United States, Europe and Asia (except Japan where we have licensed the rights to Kissei). We in-licensed PRX302 from UVIC and Johns Hopkins. Our success will depend in large part on our ability to obtain, maintain, defend and enforce patents and other proprietary technology rights. We file and prosecute patent applications to protect our proprietary discoveries. In addition to patent protection, we also seek to rely on trade secret protection, trademark protection and know-how to expand our proprietary position around our technology, discoveries and inventions that we consider important to our business. We also seek to protect our intellectual property in part by entering into confidentiality agreements and/or invention assignment agreements with our employees, consultants, scientific advisors, and certain consultants and investigators,that grant us ownership of any discoveries or inventions made by them. Further, we seek trademark protection in Canada, the United States and certain other countries where available and when we deem appropriate. We have applied for registration of the Sophiris trademark, which we use in connection with our pharmaceutical research and development services as well as our clinical-stage product candidates in Europe, Canada, Japan and the United States.

Patents and patent applications covering PRX302 which we own or license are covered by issued patents and patent applications under the following five patent families:

- Proaerolysin Containing Protease Activation Sequences and Methods of Use for Treatment of Prostate Cancer (exclusively licensed);
- Method of Treating the Symptoms of Benign Prostatic Hyperplasia Using Modified Pore-Forming Proteins (exclusively licensed);
- Formulations and Methods of Administration (owned by us); and
- Method for Treating Prostatitis Utilizing Modified Pore-Forming Protein Proaerolysin (exclusively licensed).

We own or have exclusively licensed four issued United States patents related to our prostate program: US 7838266 (prostate cancer) expiring in 2022, US 7282476 (prostate cancer) expiring in 2023, US 7745395 (prostate cancer) expiring in 2023, and US 8278279 (prostatitis) expiring in 2029, as well as 6 issued patents in countries including Australia, China, the European Patent Office (including 17 extension states), India, Japan, and South Africa expiring in 2022, 9 patents in the European Patent Office (including 14 extension states), Japan, Korea, China, Australia, New Zealand, Israel, Singapore, and South Africa expiring in 2026, and 16 additional pending U.S. and/or foreign patent applications in Australia, Canada, the European Patent Office, India and Japan variously set to expire in 2022, 2026, 2029, or 2031. This portfolio includes issued U.S. patents that cover the composition of PRX302 or methods of using

PRX302 to treat prostatitis or prostate cancer, as well as a pending U.S. patent application that covers the method of using PRX302 to treat the symptoms of BPH. This portfolio includes two issued Chinese patents. To date, we have not sought to enforce any issued patents in China. We cannot give any assurances that we will be able to enforce our patents in China to the same degree that we could in the United States.

Technology Licenses

Exclusive License Agreement with UVIC Industry Partnerships Inc. and The Johns Hopkins University for BPH

In October 2009, we entered into an exclusive license agreement with UVIC and Johns Hopkins with respect to the use of PRX302 for the development of therapeutics for the symptoms of BPH and other non-cancer diseases and conditions of the prostate. The agreement was amended on July 1, 2010. Such amendment did not change the material terms of the agreement. We have the right to grant sublicenses to third parties under the agreement provided that such sublicenses meet certain criteria.

In order to secure the license, we paid an initial license fee of CND$45,000, or $39,000, applying the conversion rate as of the date of payment. In addition, we are required to pay an annual license maintenance fee and are obligated to pay a percentage of gross sales for licensed products sold by us, our affiliates or our sublicensees during the term of the agreement. Such percentage is in the low single-digits. Furthermore, we are required to make payments based upon the achievement of specific development and regulatory milestones separated among the indications of BPH and two additional therapeutic indications selected by us, totaling up to approximately CND$1.3 million, or $1.2 million, as converted. In the event we receive consideration for granting a sublicense, we are obligated to pay UVIC and Johns Hopkins a percentage of such consideration, which percentage is in the 10-19% range, depending upon the rights granted under the sublicense agreement. To the extent we receive any milestone payments relating to the development of therapeutics for the treatment of the symptoms of BPH under our exclusive license agreement with Kissei Pharmaceutical Co., Ltd., or Kissei, we are obligated to pay a percentage of such consideration, which percentage is in the 10-19% range, to UVIC and Johns Hopkins; however, pursuant to a separate agreement which we entered into in 2003 with Dr. J. Thomas Buckley, one of our founders, the aggregate amount of such consideration payable by us to UVIC and Johns Hopkins is reduced by 25%.

Table Of Contents

Under the terms of the agreement, we are required to use reasonable commercial efforts to develop and commercialize the technology covered by the agreement, and in this regard, we have agreed to put a business plan covering the marketing and commercialization of such technology in place. Our failure to commercialize the technology covered by the agreement may result in termination of the agreement.

The term of the agreement will, on a country-by-country basis, continue until expiration of the last to expire issued patent or, if no patent has issued in such country, then 20 years after the effective date of the agreement. UVIC and Johns Hopkins have a unilateral right to terminate the agreement upon notice if we become insolvent, cease to carry out our business, subject the licensed technology to any third-party security interest or breach any of our obligations under this agreement if such breach has remained uncured for 60 days following written notice thereof. In addition, the agreement may automatically terminate in the event we undergo bankruptcy proceedings.

Exclusive License Agreement with UVIC Industry Partnerships Inc. and The Johns Hopkins University for Prostate Cancer

In September 2004, we entered into an exclusive license agreement with UVIC and Johns Hopkins, with respect to the use of PRX302 for the development of therapeutics for prostate cancer. This agreement was amended on December 8, 2004 and July 1, 2010. Such amendments did not change the material terms of the agreement. For the term of this agreement, we have an exclusive right of first option to obtain a license for future improvements to the patent rights covered by the agreement. In addition, we have the right to grant sublicenses to third parties under the agreement provided that such sublicenses meet certain criteria.

In order to secure the license, we paid an initial license fee of CND$75,000, or $62,000, applying the conversion rate as of the date of payment, and a reimbursement fee of CND$28,000, or $24,000, applying the conversion rate as of the date of payment, to cover expenses associated with the filing and maintenance fees of patents covered by the agreement. In addition, we are required to pay an annual license maintenance fee and are obligated to pay a percentage of gross sales for licensed products sold by us, our affiliates or our sublicensees during the term of the agreement. Such percentage is in the low single-digits and is subject to adjustment in certain circumstances. We are also required to make payments based upon the achievement of specific development and regulatory milestones totaling up to approximately CND$3.6 million, or $3.4 million, as converted. In the event we receive consideration for granting a sublicense, we are obligated to pay UVIC and Johns Hopkins a percentage of such consideration, which percentage is in the 20-29% range, including any future consideration we may receive under our exclusive license agreement with Kissei relating to development of therapeutics for the treatment of prostate cancer. Furthermore, we issued 3,420 common shares to Johns Hopkins and 1,710 common shares to UVIC in partial consideration for the rights granted to us under the agreement.

Under the terms of the agreement, we are required to use reasonable commercial efforts to develop and commercialize the technology covered by the agreement, and in this regard, have agreed to put a business plan in place. Our failure to commercialize the technology covered by the agreement may result in termination of the agreement.

The term of the agreement will, on a country-by-country basis, continue until expiration of the last to expire issued patent or, if no patent has issued in such country, then 20 years after the effective date of the agreement.

UVIC and Johns Hopkins have a unilateral right to terminate the agreement upon notice if we become insolvent, cease to carry out our business, subject the licensed technology to any security interest or breach any of our obligations under this agreement if such breach has remained uncured for 60 days following written notice thereof. In addition, the agreement may automatically terminate in the event we undergo bankruptcy proceedings.

Strategic Relationship with Kissei Pharmaceutical Co., Ltd.

In April 2010, we entered into an exclusive license agreement with Kissei, for the development and commercialization of PRX302 (and other products covered by the licensed patents) in Japan for the treatment of the symptoms of BPH, prostate cancer, prostatitis or other diseases of the prostate. Under the terms of the license, Kissei is permitted to sublicense its rights if certain conditions are met.

In order to secure the license, Kissei paid us an up-front payment of $3.0 million. During the year ended December 31, 2013, we recorded as revenue a $5.0 million non-refundable milestone payment due from Kissei upon the achievement of certain development activities. We received payment for the milestone in April 2013. In addition, we remain eligible to receive up to approximately $67.0 million in additional payments contingent upon achievement of specified development, regulatory and commercial milestones, some of which are in Kissei's sole discretion to achieve, separated among the indications of BPH, prostate cancer, and prostatitis or other diseases of the prostate, as well as the achievement of overall accumulated gross sales levels for such indications. The additional $67.0 million of non-refundable milestone payments is comprised as follows: aggregate milestone payments of $12.0 million are related to the BPH indication, of which $7.0 million relates to the completion of regulatory approvals and $5.0 million relates to the achievement of certain product sale goals; a total of $21.0 million is related to the prostate cancer indication, of which $7.0 million relates to the completion of development activities, $7.0 million relates to the completion of regulatory approvals and $7.0 million relates to the achievement of certain product sale goals; and a total of $21.0 million is related to prostatitis or other diseases of the prostate, of which $7.0 million relates to the completion of development activities, $7.0 million relates to the completion of regulatory approvals and $7.0 million relates to the achievement of certain product sale goals. An additional $13.0 million of aggregate milestone payments are not indication specific, of which $5.0 million relates to the completion of regulatory approvals and $8.0 million relates to the achievement of certain product sale goals. In addition, we may receive a drug supply fee and royalty payments in the 20-29% range as a percentage of future net sales of licensed products sold under the agreement. The royalties payable by Kissei are subject to reductions or offsets in certain circumstances. Kissei's royalty obligations continue until the later of expiration of the last valid claim in the licensed patents covering the applicable licensed product, or 10 years after first commercial sale of such licensed product in Japan. Kissei is responsible for all costs associated with the development, regulatory approval, commercialization and marketing of PRX302 in Japan.

47

Table Of Contents

Kissei may unilaterally terminate the agreement, provided that if such termination occurs after commercial launch of a product under the agreement, Kissei must provide us with six months prior written notice. Absent early termination, the exclusive license agreement will remain in effect until Kissei or its sublicensees or affiliates discontinue the sale of products under the agreement.

Regulatory Overview

Our business and operations are subject to a variety of U.S. federal, state and local, and foreign supranational, national, provincial and municipal laws, regulations and trade practices. The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs and biologics. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, recordkeeping, approval, advertising and promotion, and export and import of our product candidate.

U.S. Government Regulation

U.S. Drug Development Process

In the United States, the FDA regulates drugs and biologic products under the Federal Food, Drug and Cosmetic Act, or FDCA, (21 U.S.C. §301, et seq), its implementing regulations, and other laws, including, in the case of biologics, the Public Health Service Act. Our product candidate, PRX302, is subject to regulation by the FDA as a biologic. Biologics require the submission of a BLA to the FDA and approval of the BLA by the FDA before marketing in the United States. The process of obtaining regulatory approvals for commercial sale and distribution and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial civil or criminal sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold on clinical trials, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil and/or criminal penalties. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulations;

- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials in the United States may begin;

- performance of adequate and well-controlled human clinical trials in accordance with the FDA's current good clinical practices, or GCP, regulations to establish the safety and efficacy of the product candidate for its intended use;

- submission to the FDA of a BLA;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced to assess compliance with the FDA's current good manufacturing practice standards, or cGMP, regulations to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

- potential audits by the FDA of the nonclinical and clinical trial sites that generated the data in support of the BLA;

- review of the BLA by an external Advisory Committee to the FDA, whose recommendations are not binding on the FDA; and

- FDA review and approval of the BLA prior to any commercial marketing or sale.

Before testing any compounds with potential therapeutic value in humans, the drug candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, stability and formulation, as well as animal studies to assess the potential toxicity and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance, or for other reasons.

Table Of Contents

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified investigators, generally physicians not employed by or under the clinical trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and effectiveness. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with GCPs. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of clinical trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The product candidate is initially introduced into a limited population of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for some diseases, or when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the disease or condition for which the product candidate is intended to gain an early indication of its effectiveness.

- *Phase 2.* The product candidate is evaluated in a limited patient population (but larger than in Phase 1) to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to assess dosage tolerance, optimal dosage and dosing schedule.

- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, and provide substantial evidence of clinical efficacy and safety in an expanded patient population (such as several hundred to several thousand) at geographically dispersed clinical trial sites. Phase 3 clinical trials are typically conducted when Phase 2 clinical trials demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile. These trials typically have at least two groups of patients who, in a blinded fashion, receive either the product or a placebo. Phase 3 clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

Post-approval studies, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication to further assess the biologic's safety and effectiveness after BLA approval. Phase 4 studies can be initiated by the drug sponsor or as a condition of BLA approval by the FDA.

Annual progress reports detailing the results of the clinical trials must be submitted to the FDA and written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the biologic and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final biologic product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests, proposed labeling and other relevant information are submitted to the FDA in the form of a BLA requesting approval to market the product for one or more specified indications. The submission of a BLA is subject to the payment of substantial user fees.

Once the FDA receives a BLA, it has 60 days to review the BLA to determine if it is substantially complete and the data is readable, before it accepts the BLA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has 12 months from submission in which to complete its initial review of a standard BLA and make a decision on the application, and eight months from submission for a priority BLA, and such deadline is referred to as the PDUFA date. The FDA does not always meet its PDUFA dates for either standard or priority BLAs. The review process and the PDUFA date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA date.

Table Of Contents

After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug or biological products or drug or biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without an approved REMS, if required. Development of a REMS can substantially increase the costs of obtaining approval.

Before approving a BLA, the FDA will typically inspect the facilities at which the product is manufactured. The FDA will not approve the BLA unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical studies were conducted in compliance with GCP requirements. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information before a BLA can be approved.

The FDA will issue a complete response letter if the agency decides not to approve the BLA. The complete response letter describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post marketing studies, sometimes referred to as Phase 4 testing, which involves clinical trials designed to further assess drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, certain changes to the approved biologic, such as adding new indications, manufacturing changes or additional labeling claims, are subject to further FDA review and approval. Depending on the nature of the change proposed, a BLA supplement must be filed and approved before the change may be implemented. For many proposed post-approval changes to a BLA, the FDA has up to 180 days to review the application. As with new BLAs, the review process is often significantly extended by the FDA requests for additional information or clarification.

Post-Approval Requirements

Any biologic products for which we or our collaborators receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements, which include, among others, restrictions on direct-to-consumer advertising, promoting biologics for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. The FDA closely regulates the post-approval marketing and promotion of biologics, and although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Failure to comply with these or other FDA requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action, mandated corrective advertising or communications with healthcare professionals, possible civil or criminal penalties, or other negative consequences, including adverse publicity.

We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Our collaborators may also utilize third parties for some or all of a product we are developing with such collaborator. Manufacturers are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Table Of Contents

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our biologic product candidate, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications of other companies seeking to reference another company's BLA. We believe that if PRX302 is approved as a biological product under a BLA, it should qualify for a 12-year period of exclusivity currently permitted by the Biologics Price Competition and Innovation Act of 2009, or BPCIA. Specifically, the BPCIA established an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on their similarity to existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator BLA holder. The BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is subject to uncertainty.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

U.S. Federal and State Fraud and Abuse Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the biopharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not satisfy the requirements of an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor, including commercial payors. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer’s products from reimbursement under government programs, criminal fines, and imprisonment.

Table Of Contents

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If we obtain FDA approval for our product candidate and begin commercializing that product in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute. We are also subject to:

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

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

In the United States and foreign jurisdictions, there have been and continue to be a number of initiatives that seek to reduce healthcare costs. Most recently, in March 2010 the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, was enacted, which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;

- new requirements to report certain financial arrangements with physicians and others, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and

- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, it remains unclear the full effect that the PPACA would have on our business.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we, and our collaborators, will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we, or our collaborators, obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country.

If we, or our collaborators, fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations.

52

Table Of Contents

Employees

As of March 31, 2014, we had ten full-time employees, four of whom have Ph.D. or M.D. degrees. None of our employees are covered by collective bargaining agreements and we consider relations with our employees to be good.

Facilities

Our corporate headquarters are located in San Diego, California. The facility we lease encompasses approximately 2,000 square feet of office space. The lease for this facility expires in May 2017. We believe that our facility is sufficient to meet our needs and that suitable additional space will be available as and when needed.

Legal Proceedings

We are not a party to any material litigation or proceeding and are not aware of any material litigation or proceeding, pending or threatened against us.

Corporate Information

We file annual, quarterly, current reports, proxy statements and other information with the Securities and Exchange Commission (SEC). Our primary website can be found at http://www.sophiris.com. We make available free of charge at this website (under the “Investors — Financial Information” caption) all of our reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, including our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K and amendments to those reports. These reports are made available on the website as soon as reasonably practicable after their filing with, or furnishing to, the SEC. The SEC maintains an internet site that contains our public filings with the SEC and other information regarding the Company, at www.sec.gov. These reports and other information concerning the Company may also be accessed at the SEC’s Public Reference Room at 100 F Street, NE, Washington DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Furthermore, we also make available on our website free of charge, and in print to any shareholder who requests it, the Committee Charters for our Audit, Compensation, and Governance and Nominating Committees, as well as the Code of Business Conduct and Ethics that applies to all directors, officers and employees of the Company. Amendments to these documents or waivers related to the Code of Business Conduct and Ethics will be made available on our website as soon as reasonably practicable after their execution. The contents of the websites referred to in this paragraph are not

incorporated into this Annual Report. Further, our references to the URLs for these websites are intended to be inactive textual reference only.

We are governed by the Business Corporations Act of British Columbia. We began operations on January 11, 2002. Our operations were initially located in Vancouver, British Columbia. In April 2011, we relocated our core activities and headquarters from Vancouver, British Columbia to San Diego, California. Effective April 2, 2012, we changed our name from Protox Therapeutics Inc. to Sophiris Bio Inc.

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering in August 2013, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the “JOBS Act,” and references herein to “emerging growth company” shall have the meaning associated with it in the JOBS Act.”

Table Of Contents

MANAGEMENT

Please see the sections entitled “Election of Directors,” “Executive Officers” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on April 7, 2014, which are incorporated herein by reference.

EXECUTIVE AND DIRECTOR COMPENSATION

Please see the section entitled “Executive and Director Compensation” in our Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on April 7, 2014, which is incorporated herein by reference.

Table Of Contents

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2011 to which we have been a party, in which the amount involved in the transaction exceeded $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation." We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions.

Requirements under the BCBCA and the Company's Articles

To the best of our knowledge, there are no existing or potential conflicts of interest between the company and any of our directors or officers as a result of such individual's outside business interests at the date hereof. However, certain of our directors and officers are, or may become, directors or officers of other companies with businesses which may conflict with our business. Accordingly, conflicts of interest may arise which could influence these individuals in evaluating possible transactions or in generally acting on behalf of the company. Pursuant to the BCBCA, directors are required to act honestly and in good faith with a view to the best interests of the company. As required under the BCBCA and our articles:

- A director or executive officer who holds any office or possesses any property, right or interest that could result, directly or indirectly, in the creation of a duty or interest that materially conflicts with that individual's duty or interest as a director or executive officer of the company, must promptly disclose the nature and extent of that conflict.

- A director who holds a disclosable interest (as that term is used in the BCBCA) in a contract or transaction into which we have entered or proposes to enter may generally not vote on any directors' resolution to approve the contract or transaction.

Generally, as a matter of practice, directors or executive officers who have disclosed a material interest in any transaction or agreement that our Board is considering will not take part in any Board discussion respecting that contract or transaction. If such directors were to participate in the discussions, they would abstain from voting on any matters relating to matters in which they have disclosed a material interest. In appropriate cases, we will establish a special committee of independent directors to review a matter in which directors, or management, may have a conflict.

Requirements under Applicable Canadian Securities Laws

We are subject to Multilateral Instrument 61 – 101 – *Protection of Minority Security Holders in Special Transactions*, or MI 61-101, which imposes minority shareholder approval, valuation and disclosure requirements on entities involved in certain transactions with related parties. A related party includes a person that, at the relevant time and after reasonable inquiry, is known by the company or a director or officer of the company to be a control person of the company. It also includes a person that has beneficial ownership of or control or direction over, directly or indirectly, securities of the company carrying more than 10% of the voting rights attached to all the outstanding voting securities of the company and an affiliate of the related party.

A related party transaction means a transaction between the company and a person that is a related party of the company at the time the transaction is agreed to, whether or not there are also other parties to the transaction, as a consequence of which, either through the transaction itself or together with connected transactions, among other things, the company directly or indirectly (a) acquires an asset from the related party for valuable consideration or disposes of any asset to the related party, (b) acquires or disposes of, as a joint actor with the related party, an asset from a third party if the proportion of the asset acquired or consideration received by the company is less than the proportion of the consideration paid or asset disposed of by the company, (d) acquires the related party, or combines with the related party, through an amalgamation, arrangement or otherwise, whether alone or with joint actors, (e) issues a security to the related party or subscribes for a security of the related party, (f) assumes or otherwise becomes subject to a liability of the related party or forgives a debt owed by the related party, (g) borrows money from or lends money to the related party.

Unless a specific exemption is available under MI 61-101, a reporting company involved in a related party transaction is required to obtain minority approval of the related party transaction in accordance with the requirements of MI 61-101. Minority approval means, for a related party transaction of a company, approval of the proposed transaction by a majority of the votes cast by holders of affected securities at a meeting of security holders called to consider the transaction, excluding the votes owned or controlled by the company and the related party and certain other interested parties. Where multiple classes of affected securities may have differing interests, minority approval will be required of each class at separate meetings of each such class. There are specific rules in MI 61-101 regarding obtaining minority approval, including the determination of the votes to be excluded from the minority approval and the disclosure required to be included in the information circular sent to security holders.

Table Of Contents

Unless a specific exemption is available under MI 61-101, a reporting company involved in a related party transaction is required to obtain a formal valuation for certain related party transactions, including any business combination transaction where a related party would directly or indirectly acquire the company or the its business or combine or amalgamate with the company, or for any transaction noted above in paragraphs (a) to (e).

A company will be required to include certain detailed disclosure regarding related party transactions in a material change report that is required to be filed under applicable securities laws for the related party transaction and in any information circular that is sent to security holders in connection with obtaining minority approval.

Private Placements

In September 2010, we entered into an investment agreement, or the Investment Agreement, with Warburg Pincus Private Equity X, L.P. and Warburg Pincus X Partners, L.P., which we refer to together as Warburg Pincus, whereby Warburg Pincus could invest up to CND$35.0 million, or $34.0 million, as converted, applying the conversion rate as of the date of the agreement, through a unit offering at CND$20.80 per unit, or $20.28 per unit, as converted, applying the conversion rate as of the date of the agreement, with each unit consisting of one of our common shares and 0.6 of a common share purchase warrant. Each whole warrant entitles the holder to purchase one of our common shares at a price of CND$26.00, or $24.96, as converted, exercisable for a period of five years from the date of issue, subject to the acceleration of the expiration date in certain circumstances at our option, in which case the warrant would be exercised automatically. The investment consisted of an initial tranche of CND$10 million, or $9.8 million, as converted, applying the conversion rate as of the date of closing in November 2010, a second tranche of CND$8.3 million, or $8.1 million, as converted, applying the conversion rate as of the date of closing in December 2011 and a third tranche of CND$8.3 million, or $8.3 million, as converted, applying the conversion rate as of the date of closing in March 2012. Warburg Pincus' ability to make additional investments under the Investment Agreement expired effective September 30, 2012 and the investment Agreement was terminated in July 2013. Two of our former directors, Amit Sobti and Noah Knauf were affiliated with Warburg Pincus.

Warrant Amendments

In January 2014, we entered into an omnibus amendment to common shares purchase warrants, or the Warburg Warrant Amendment, related to Warburg Pincus Private Equity X, L.P.'s and Warburg Pincus X Partners, L.P.'s outstanding common share purchase warrants. The Warburg Warrant Amendment provides for an amendment to the exercise price and number of shares underlying each of the outstanding common share purchase warrants to reflect the 52-for-1 share consolidation effected by us in August 2013 and an amendment of the existing exercise price which was denominated in Canadian dollars to be restated into U.S. dollars. The conversion of the exercise price was completed utilizing the exchange rate in effect on the date of issuance of each warrant. No new common share purchase warrants were issued as a result of the execution of the Warburg Warrant Amendment.

In February 2014, we entered into an omnibus amendment to warrants to purchase common shares, or the Oxford Warrant Amendment, related to Oxford Finance LLC's outstanding common share purchase warrants. The Oxford Warrant Amendment provides for an amendment to the exercise price and number of shares underlying each of the outstanding common share purchase warrants to reflect the 52-for-1 share consolidation effected by us in August 2013 and an amendment of the existing exercise price which was denominated in Canadian dollars to be restated into U.S. dollars. The conversion of the exercise price was completed utilizing the exchange rate in effect on the date of issuance of each warrant. No new common share purchase warrants were issued as a result of the execution of the Oxford Warrant Amendment.

Employment Arrangements

We entered into written employment agreements or offer letters with Randall E. Woods, Dr. Allison Hulme, and Peter Slover. We entered into a Settlement Agreement and Release with each of Dr. Merchant and Ms. Merchant, our former Chief Executive Officer and President and Senior Vice President, Development and Regulatory Affairs, respectively. Both Dr. Merchant and Ms. Merchant entered into a consulting agreement to provide certain consulting services to us following termination of employment. We also entered into a separation agreement with Mr. Casdin, our former Chief Financial Offer, in connection with his resignation of employment with us in September 2012. Pursuant to the separation agreement, Mr. Casdin agreed to a release of claims against the company and was entitled to receive certain severance benefits, including continued base salary and health insurance payments, as well as stock option vesting acceleration. For more information, refer to "Executive and Director Compensation" in our Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on April 7, 2014, which is incorporated herein by reference.

Stock Options Granted to Executive Officers and Directors

We have granted stock options to our executive officers and directors, as more fully described in "Executive and Director Compensation."

Table Of Contents

Indemnification Agreements

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors in addition to the indemnification provided for under the BCBCA and in our articles. These agreements, among other things, require us to indemnify our directors for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director in any action or proceeding arising out of their services as one of our directors or any other company or enterprise to which the person provides services at our request. We believe that these indemnification agreements are necessary to attract and retain qualified persons as directors.

The limitation of liability and the indemnification provisions in these indemnification agreements and in our articles and under the BCBCA may discourage shareholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our shareholders. A shareholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Investment Agreement

In connection with the September 2010 private placement, we entered into the Investment Agreement which provided Warburg Pincus, a holder of more than 5% of our outstanding share capital, with certain information rights, preemptive rights, and defensive measures, among other things. The Investment Agreement was terminated in July 2013.

Registration Rights Agreement

We are party to a Registration Rights Agreement, dated November 19, 2010, that provides Warburg Pincus, a holder of more than 5% of our outstanding share capital, with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. For a more detailed description of these registration rights, see "Description of Share Capital – Registration Rights."

Policies and Procedures for Transactions with Related Persons

In connection with our initial public offering, we adopted a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our common shares, and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the prior consent of our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of our common shares, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds $120,000 and such person would have a direct or indirect interest must first be presented to our audit committee for review, consideration, and approval. In approving or rejecting any such proposal, our audit committee is to consider the relevant facts and circumstances of the proposed transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction. We did not have a formal review and approval policy for related party transactions at the time of some of the transactions described above. However, all of the transactions described above were entered into after presentation, consideration, and approval by our board of directors.

Table Of Contents

PRINCIPAL SHAREHOLDERS

The following table sets forth information regarding beneficial ownership of our share capital as of April 30, 2014 by: (1) each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common shares; (2) each of our directors; (3) each of our named executive officers; and (4) all of our directors and current executive officers as a group.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Sophiris Bio Inc., 1258 Prospect Street, La Jolla, California 92037.

	Beneficial Ownership		
Name and address of beneficial owner	**Number of shares**	**Percent of Total**	
5% or greater shareholders			
Tavistock Life Sciences Co.[1] 440 Stevens Ave, Suite 100 Solana Beach, CA 92075	2,561,538	15.9	%
T. Rowe Price Associates Inc.[2]. 100 E. Pratt Street Baltimore, MD 21202	1,614,228	10.0	%
Great Point Partners LLC[3] 165 Mason Street, 3rd Floor Greenwich, CT 06830	1,379,660	8.5	%
Warburg Pincus Private Equity X, L.P.[4] 450 Lexington Avenue New York, NY 10017	1,089,744	6.4	%
Invus Public Equities, L.P.[5] 750 Lexington Avenue, 30th Floor New York, NY 10022	1,000,000	6.2	%
Directors and named executive officers			
Randall E. Woods[6]	43,999	*	
Allison Hulme[7]	22,102	*	
Peter T. Slover[8]	16,898	*	

Lars Ekman[9]	31,701	*	
John Geltosky[10]	9,306	*	
Jim Heppell[11]	253,934	1.6	%
Gerald T. Proehl[12]	1,375	*	
Joseph L. Turner[13]	8,250	*	
All current executive officers and directors as a group (nine persons)[14]	400,814	2.5	%

*Represents beneficial ownership of less than 1% of our outstanding common shares.

(1) The information in the table and this note is derived from a Schedule 13G filed by Tavistock Life Sciences Co. with the Securities and Exchange Commission, or the SEC, on August 26, 2013. Consists of 2,315,385 common shares of the Company that are beneficially owned by Boxer Capital, LLC, or Boxer Capital, and 246,143 common shares of the Company that are beneficially owned by MVA Investors, LLC (MVA). Boxer Management is the managing member and majority owner of Boxer Capital. Joseph Lewis is the sole indirect owner and controls Boxer Management. MVA is the independent, personal investment vehicle of certain employees of Boxer Capital and Tavistock Life Sciences Company, which is a Delaware corporation and an affiliate of Boxer Capital and is controlled by employees of Tavistock Life Sciences Company that are members of MVA investors. As such, MVA Investors is not controlled by Boxer Capital, Boxer Management or Joseph Lewis. MVA is primarily engaged in the business of investing in securities. The principal business address of Boxer Capital, and MVA is: 440 Stevens Avenue, Suite 100, Solana Beach, CA 92075. The principal business address of both Boxer Asset Management and Joseph Lewis is: c/o Cay House P.O. Box N-7776 E.P. Taylor Drive Lyford Cay, New Providence, Bahamas.

(2) The information in the table and this note is derived from a Schedule 13G filed by T. Rowe Price Associates, Inc. on February 14, 2014. T. Rowe Price Associates, Inc., or Price Associates, has sole voting power over 198,416 of such common shares and sole dispositive power over 1,614,228 of such common shares. Price Associates has advised us that these securities are owned by various individual and institutional investors with respect to which Price Associates serves as investment adviser with power to direct investments and/or sole power to vote the securities. For purposes of the reporting requirements of the Securities Exchange Act of 1934, the Exchange Act, Price Associates is deemed to be a beneficial owner of such securities; however, Price Associates expressly disclaims that it is, in fact, the beneficial owner of such securities.

Table Of Contents

(3) The information in the table and this note is derived from a Schedule 13G/A filed by Great Point Partners, LLC with the SEC on February 14, 2014. Consists of 1,379,660 common shares beneficially owned by Great Point Partners, LLC (Great Point), Dr. Jeffrey R. Jay, M.D., and Mr. David Kroin which have shared voting and dispositive power. Biomedical Value Fund, L.P. (BVF) is the direct beneficial owner of 334,168 shares. Biomedical Offshore Value Fund, Ltd. (BOVF) is the direct beneficial owner of 334,168 shares. Biomedical Institutional Value Fund, L.P. (BIVF) is the direct beneficial owner of 198,697 shares. Class D Series of GEP-PS, LP is the direct beneficial owner of 230,348. WS Investment II, LLC (WS) is the direct beneficial owner of 55,284 shares. David J. Morrison (Morrison) is the direct beneficial owner of 9,214 shares. Great Point is the investment manager of BVF, BOVF, BIVF, WS and Morrison, and by virtue of such status may be deemed to be the beneficial owner of the BVF, BOVF and BIVF, WS and Morrison shares. Each of Dr. Jeffrey R. Jay, M.D. (Dr. Jay), as senior managing member of Great Point, and Mr. David Kroin (Mr. Kroin), as special managing member of Great Point, has voting and investment power with respect to the BVF, BOVF, BIVF, WS and Morrison shares, and therefore may be deemed to be the beneficial owner of the BVF, BOVF, BIVF, WS and Morrison shares. Notwithstanding the above, Great Point, Dr. Jay and Mr. Kroin disclaim beneficial ownership of the BVF, BOVF, BIVF, US and Morrison shares, except to the extent of their respective pecuniary interests.

(4) Consists of 320,513 common shares and 769,231 common share purchase warrants that are immediately exercisable by Warburg Pincus Private Equity X, L.P. and Warburg Pincus X Partners, L.P., both Delaware limited partnerships, together, WP X. Warburg Pincus X, L.P., a Delaware limited partnership, or WP X GP, is the general partner of WP X. Warburg Pincus X LLC, a Delaware limited liability company, or WP X LLC, is the general partner of WP X GP. Warburg Pincus Partners LLC, a New York limited liability company, or WP Partners, is the sole member of WP X LLC. Warburg Pincus & Co., a New York general partnership, or WP, is the managing member of WP Partners. Warburg Pincus LLC, a New York limited liability company, or WP LLC, is the manager of WP X. Charles R. Kaye and Joseph P. Landy are each Managing General Partners of WP and Managing Members and Co-Presidents of WP LLC and may be deemed to control the Warburg Pincus entities. Messrs. Kaye and Landy disclaim beneficial ownership of all shares held by the Warburg Pincus entities.

(5) The information in the table and this note is derived from a Schedule 13G filed by Invus Public Equities, L.P. with the SEC on August 16, 2013. Consists of 1,000,000 shares held by Invus Public Equities, L.P, Invus Public Equities Advisors, LLC, Artal International S.C.A., Artal International Management S.A., Artal Group S.A., Westend S.A., Stichting Administratiekantoor Westend and Mr. Pascal Minne all of which have shared voting and shared dispositive power over the shares.

(6) Includes 12,500 shares and 31,499 shares subject to options exercisable within 60 days of April 30, 2014.

(7) Includes 22,102 shares subject to options exercisable within 60 days of April 30, 2014.

(8) Includes 4,680 shares and 16,898 shares subject to options exercisable within 60 days of April 30, 2014.

(9) Includes 10,183 shares and 21,518 shares subject to options exercisable within 60 days of April 30, 2014.

(10) Includes 9,306 shares subject to options exercisable within 60 days of April 30, 2014.

(11) Includes 11,150 shares and 10,652 shares subject to options exercisable within 60 days of April 30, 2014. Also includes 188,560 shares and 21,368 common share purchase warrants beneficially owned by B.C. Advantage Funds (VCC) Ltd., 19,231 shares owned by Lions Liquidity Investment Fund I Limited Partnership and 630 shares and 2,344 common share purchase warrants owned by Lions Capital Corp., for which Mr. Heppell may be deemed to share voting and investment control. The share and common share purchase warrants beneficially owned by B.C. Advantage Funds (VCC) Ltd. have been pledged as security. Mr. Heppell disclaims ownership of such shares held by B.C. Advantage Funds (VCC) Ltd., Lions Liquidity Investment Fund I Limited Partnership

and Lions Capital Corp., except to the extent of his pecuniary interest therein, if any.

(12) Includes 1,375 shares subject to options exercisable within 60 days of April 30, 2014.

(13) Includes 8,250 shares subject to options exercisable within 60 days of April 30, 2014.

(14) Includes the shares and shares subject to options exercisable within 60 days of April 30, 2014 referred to in footnotes (6), (7), (8), (9), (10), (11), (12) and (13).

Table Of Contents

DILUTION

The sale of our common stock to Aspire Capital pursuant to the Purchase Agreement will have a dilutive impact on our stockholders. As a result, our net income per share, if any, would decrease in future periods and the market price of our common stock could decline. In addition, the lower our stock price is at the time we exercise our right to sell shares to Aspire Capital, the more shares of our common stock we will have to issue to Aspire Capital pursuant to the Purchase Agreement and our existing stockholders would experience greater dilution.

After giving effect to the sale pursuant to the Purchase Agreement of 3,409,629 shares of common stock at an assumed average sale price of $3.11 per share (based on the lowest sales price of our common stock as of May 22, 2014), our pro forma as adjusted net tangible book value as of December 31, 2013 would have been approximately $50.8 million, or $2.60 per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of $0.10 per share to our existing stockholders and an immediate dilution of $0.51 per share to our new stockholders.

Table Of Contents

Selling Shareholder

The selling shareholder may from time to time offer and sell any or all of our common shares set forth below pursuant to this prospectus. When we refer to the "selling shareholder" in this prospectus, we mean the entity listed in the table below, and its respective pledgees, donees, permitted transferees, assignees, successors and others who later come to hold any of the selling shareholder's interests in our common shares other than through a public sale.

The following table sets forth, as of the date of this prospectus, the name of the selling shareholder for whom we are registering shares for sale to the public, the number of common shares beneficially owned by the selling shareholder prior to this offering, the total number of common shares that the selling shareholder may offer pursuant to this prospectus and the number of common shares that the selling shareholder will beneficially own after this offering. Except as noted below, the selling shareholder does not have, or within the past three years has not had, any material relationship with us or any of our predecessors or affiliates and the selling shareholder is not or was not affiliated with registered broker-dealers.

Based on the information provided to us by the selling shareholder, assuming that the selling shareholder sells all of our common shares beneficially owned by it that have been registered by us and does not acquire any additional shares during the offering, the selling shareholder will not own any shares other than those appearing in the column entitled "Beneficial Ownership After this Offering." We cannot advise you as to whether the selling shareholder will in fact sell any or all of such common shares. In addition, the selling shareholder may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, our common shares in transactions exempt from the registration requirements of the Securities Act of 1933 after the date on which it provided the information set forth in the table below.

			Beneficial Ownership After this Offering (1)	
Name	**Common Shares Owned Prior to this Offering**	**Common Shares Being Offered**	**Number of Shares**	**% (2)**
Aspire Capital Fund, LLC (3)	694,865 (4)	2,714,764	0	*

* Represents less than 1% of outstanding shares.

(1) Assumes the sale of all common shares registered pursuant to this prospectus, although the selling shareholder is under no obligation known to us to sell any common shares at this time.

(2) Based on 16,844,736 common shares outstanding on May 28, 2014.

(3) Aspire Capital Partners, LLC is the managing member of Aspire Capital Fund, LLC. SGM Holdings Corp. is the managing member of Aspire Capital Partners, LLC. Steven G. Martin is the president and sole shareholder of SGM Holdings Corp. Erik J. Brown is a principal of Aspire Capital Partners, LLC. Christos Komissopoulos is a principal of Aspire Capital Partners, LLC. Each may be deemed to have shared voting and investment power over shares owned by Aspire Capital Fund, LLC. Each of Aspire Capital Partners, LLC, SGM Holdings Corp., Mr. Martin, Mr. Brown and Mr. Komissopoulos disclaims beneficial ownership of the common shares held by Aspire Capital Fund, LLC. Aspire Capital is not a licensed broker dealer or an affiliate of a licensed broker dealer.

(4) As of the date hereof, 694,865 of our common shares have been acquired by Aspire Capital under the Purchase Agreement, consisting of Commitment Shares issued to Aspire Capital and the Initial Purchase Shares sold to Aspire Capital. We may elect in our sole discretion to sell to Aspire Capital up to an additional 2,714,764 shares under the Purchase Agreement and included in this prospectus but Aspire Capital does not presently beneficially own those shares as determined in accordance with the rules of the SEC.

Table Of Contents

DESCRIPTION OF SHARE CAPITAL

Our authorized capital consists of unlimited common shares, with no par value, and unlimited preferred shares, with no par value. The following is a summary of the rights of our common and preferred shares and some of the provisions of our notice of articles and articles. This summary is not complete. For more detailed information, please see our notice of articles and articles, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the BCBCA.

Common Shares

Outstanding Shares

As of April 30, 2014, 16,149,871 of our common shares were outstanding, held by 26 shareholders of record and none of our preferred shares were outstanding. If we sell and issue all 3,409,629 additional common shares available for issuance to Aspire Capital, pursuant to the Purchase Agreement, 19,559,500 of our common shares will be outstanding.

As of April 30, 2014, approximately 6% of our outstanding common shares were held by five shareholders of record in the United States.

Market Information

Our common shares are currently traded on the NASDAQ Global Market, or NASDAQ, under the symbol “SPHS.” Prior to our initial public offering on the NASDAQ on August 16, 2013 we were traded on the Toronto Stock Exchange, or TSX, under the symbol “SHS.” For the period from August 16, 2013 to November 13, 2013 we were dual listed on both the NASDAQ and the TSX. Effective November 13, 2013, we voluntarily delisted our common shares from the TSX.

The following table sets forth the high and low sales prices for our common shares for the period January 1, 2011 through November 13, 2013, on the TSX, quoted in Canadian Dollars and August 16, 2013 through May 16, 2014 on NASDAQ, quoted in United States Dollars. The high and low sales prices below reflect the 52-for-1 reverse share

consolidation which was effected on August 9, 2013.

	NASDAQ		TSX	
	US$	US$	CND$	CND$
2011	**High**	**Low**	**High**	**Low**
First Quarter	—	—	$39.52	$24.44
Second Quarter	—	—	39.00	26.00
Third Quarter	—	—	29.12	13.00
Fourth Quarter	—	—	22.36	14.82
2012				
First Quarter	—	—	$21.32	$15.08
Second Quarter	—	—	28.60	14.82
Third Quarter	—	—	21.32	15.60
Fourth Quarter	—	—	16.64	11.44
2013				
First Quarter	—	—	$15.34	$8.84
Second Quarter	—	—	18.20	10.40
Third Quarter (commencing August 16, 2013 for NASDAQ)	$5.00	$4.10	14.82	4.30
Fourth Quarter (ending November 13, 2013 for TSX)	4.85	3.50	5.06	4.36
2014				
First Quarter	$5.18	$3.22	—	—
Second Quarter (through June 16, 2014)	$3.73	$2.25	—	—

Share Capital

Common Shares

The holders of common shares are entitled to receive notice of any meeting of our shareholders, except those meetings at which only the holders of shares of another class or of a particular series are entitled to vote separately as a class or series, and to attend any such meeting and vote their common shares on all matters submitted to a vote of the shareholders, including the election of directors. Each common share entitles its holder to one vote. Our notice of articles and articles do not provide for cumulative voting rights. Because of this, the holders of a majority of the common shares entitled to vote in any election of directors can elect all of the directors standing for election. Shareholder resolutions are generally required to be approved by a majority of votes cast by shareholders, who vote in person or by proxy, in respect of the resolution. However, the BCBCA and our articles require that certain extraordinary corporate actions, such as amalgamations (other than with certain affiliated corporations), continuances, liquidations, dissolutions, arrangements, and sales, leases or exchanges of all, or substantially all, of the assets of the corporation other than in the ordinary course of business, are required to be approved by a “special resolution”, where a special majority of two-thirds of the votes cast by shareholders, who vote in person or by proxy, in respect of the resolution. Subject to the rights of the holders of preferred shares, the holders of common shares are entitled to receive, on a pro-rata basis, such dividends as our board of directors may declare out of funds legally available for this purpose. In the event of the dissolution, liquidation, winding-up or other distribution of our assets, such holders are entitled to receive, on a pro-rata basis, all of our assets remaining after payment of all of our liabilities, subject to the rights of holders of preferred shares. Otherwise, the common shares carry no preemptive, conversion or subscription

rights. All of our outstanding common shares are duly authorized, validly issued, fully paid and nonassessable.

Table Of Contents

Preferred Shares

Our board of directors may authorize the issuance of preferred shares from time to time in one or more series, each series comprising the number of shares, designation, rights, privileges, restrictions and conditions determined by our board of directors. The preferred shares may have voting or conversion rights that could have the effect of restricting dividends on our common shares, diluting the voting power of our common shares, impairing the rights of our common shares in the event of our dissolution, liquidation or winding-up or otherwise adversely affect the rights of holders of our common shares. The issuance of preferred shares, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change of control and may adversely affect the market price of our common shares and may preclude shareholders from realizing a potential premium over the market value of their shares. The holders of preferred shares are entitled to receive notice of any meeting of our shareholders and to attend and vote, except as otherwise provided in the rights and restrictions attached to the shares by the board of directors. As at the date hereof, there were no preferred shares issued and outstanding.

Warrants

As of April 30, 2014, there were 918,868 common share purchase warrants outstanding, which expire between March 2015 and July 2018. Each of these warrants entitles the holder to purchase one common share at prices ranging between $25.54 and $30.84 per common share. Each of these warrants has a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common shares at the time of exercise of the warrant after deduction of the aggregate exercise price. Each of these warrants also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of dividends, stock splits, reorganizations and reclassifications and consolidations. Certain of these warrants may be subject to an acceleration of their expiration dates if certain conditions are met.

Registration Rights

Warburg Pincus is entitled to rights with respect to the registration of certain of its securities under the Securities Act. These registration rights are contained in the registration rights agreement, dated as of November 19, 2010, between us and Warburg Pincus, or the Registration Rights Agreement, and are described in additional detail below. In an underwritten offering, the underwriters have the right, subject to specified conditions, to limit the number of registrable securities (as such term is defined in the Registration Rights Agreement) to be included under a registration statement.

63

Table Of Contents

Demand Registration Rights

Warburg Pincus has the right to demand from us the registration of its registrable securities on (i) Form S-1, Form F-1, Form S-3, or Form F-3 in the United States, provided that we qualify to use such Form S-3 or Form F-3, or (ii) pursuant to a long or short form prospectus in Canada, provided that we qualify to use such short form, in each case so long as the aggregate value of the securities entitled to be included under such registration statement is at least $5.0 million with respect to registration in the United States and CND$5.0 million, or $5.1 million, as converted, with respect to registration in Canada, subject to specified limitations.

“Piggyback” Registration Rights

Subject to specified exceptions, if we propose to register any securities for our own or others’ account, Warburg Pincus has the right to register its shares under the proposed registration statement.

Expenses of Registration; Indemnification

Generally, we are required to bear all registration and selling expenses incurred in connection with each of the registrations described above, other than underwriting discounts, commissions and transfer taxes. The Registration Rights Agreement contains customary indemnification provisions.

Current Reports

We have agreed, under the Registration Rights Agreement, to file the reports required under the Securities Act and applicable Canadian securities legislation to enable the holders of registrable securities to sell such securities pursuant to Rules 144, 144A, Regulation S or applicable Canadian securities legislation.

Waiver of Rights

In connection with the registration statement of which this prospectus forms a part, each shareholder that has registration rights has waived such registration rights in connection with such registration statement.

Incentive Stock Options

We have an incentive stock option plan, the Plan, under which outstanding stock options (all of which are non-transferable) to purchase 1,364,223 common shares have been granted and are outstanding as of April 30, 2014 to certain executive officers, directors, consultants and employees of the company. The number of common shares available for purchase pursuant to options granted under the Plan is based on a cumulative percentage of up to a maximum of 10% of the number of common shares issued and outstanding on a particular grant date.

The Plan provides that the board of directors may from time to time grant options to any person who is an employee or director of the company or any other person or company engaged to provide services to the company. The exercise price of options granted under the Plan is determined based upon the closing trading price of the common shares on the primary organized trading facility on which the common shares are listed on the trading day immediately preceding the grant. The term of any option granted is not to exceed ten years from the date of grant. The Plan does not contemplate that we will provide financial assistance to any optionee in connection with the exercise of options. Options that have expired, been cancelled or otherwise terminated without having been exercised are available for subsequent grants under the Plan.

The Plan contains a provision whereby in the event of a “change of control” of our company, the vesting of all options would be accelerated such that non-vested options then outstanding would immediately become fully vested on the date a “change of control” was deemed to have occurred. A “change of control” is defined as and deemed to have occurred when a person or group of persons acting in concert, directly or indirectly acquires beneficial ownership of more than 50% of our then issued and outstanding common shares or a majority of directors elected at any annual or special general meeting of shareholders of the company are not individuals nominated by the our then-incumbent board of directors. Neither of these events occurred during 2012 nor to-date. The Plan was last ratified by our shareholders at our annual meeting for 2012.

Amendment to our Articles

Provisions in the BCBCA and in our articles require approval of our board of directors and the holders of a special majority of our outstanding share capital to amend our articles and our notice of articles, being two-thirds of the votes cast in person or by proxy at a shareholders meeting.

Table Of Contents

Ownership and Exchange Controls

There is currently no law, governmental decree or regulation in Canada that restricts the export or import of capital, or which would affect the remittance of dividends, interest or other payments by us to non-resident holders of our common shares, other than withholding tax requirements, as discussed below under “Certain Canadian Federal Income Tax Information.”

There is currently no limitation imposed by Canadian law or our notice of articles or articles on the right of non-residents to hold or vote our common shares, other than those imposed by the Investment Canada Act and the Competition Act (Canada). These acts will generally not apply except where a control of an existing Canadian business or company, which has Canadian assets or revenues over a certain threshold, is acquired and will not apply to trading generally of securities listed on a stock exchange.

Listing on the NASDAQ Global Market

Our common shares currently trade on the NASDAQ Global Market under the symbol “SPHS.”

Transfer Agent and Registrar

The transfer agent and registrar for our common shares in the United States and Canada is Computershare Investor Services Inc.

Table Of Contents

PLAN OF DISTRIBUTION

The common shares offered by this prospectus are being offered by Aspire Capital, the selling shareholder. The common shares may be sold or distributed from time to time by the selling shareholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common shares offered by this prospectus may be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- "at the market" into an existing market for the common shares;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

The selling shareholder may also sell common shares under Rule 144 promulgated under the Securities Act of 1933, as amended, or the Securities Act, if available, rather than under this prospectus. In addition, the selling shareholder may transfer the common shares by other means not described in this prospectus.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling shareholder and/or purchasers of the common shares for whom the broker-dealers may act as agent. Aspire Capital has informed us that each such broker-dealer will receive commissions from Aspire Capital which will not exceed customary brokerage commissions.

Aspire Capital is an “underwriter” within the meaning of the Securities Act.

Neither we nor Aspire Capital can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between Aspire Capital, any other shareholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling shareholder, and any other required information. Pursuant to a requirement of the Financial Industry Regulatory Authority, or FINRA, the maximum commission or discount and other compensation to be received by any FINRA member or independent broker-dealer shall not be greater than eight percent (8%) of the gross proceeds received by us for the sale of any securities being registered pursuant to Rule 415 under the Securities Act.

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have agreed to indemnify Aspire Capital and certain other persons against certain liabilities in connection with the offering of common shares offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Aspire Capital has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Aspire Capital specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Table Of Contents

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

Aspire Capital and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common shares during the term of the Purchase Agreement.

We have advised Aspire Capital that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling shareholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

We may suspend the sale of shares by Aspire Capital pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Aspire Capital.

Table Of Contents

LEGAL MATTERS

We are being represented by Cooley LLP, San Diego, California. The validity of the common shares being offered by this prospectus and legal matters relating to Canadian laws will be passed upon for us by Fasken Martineau DuMarlin LLP, Vancouver, British Columbia.

EXPERTS

The consolidated financial statements as of December 31, 2013 and December 31, 2012 and for each of the two years in the period ended December 31, 2013, and cumulatively, for the period January 1, 2012 to December 31, 2013 incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2013 have been so included in reliance on the report of PricewaterhouseCoopers LLP (U.S.), an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The consolidated statements of operations and comprehensive loss and of cash flows for the year ended December 31, 2011 and the related consolidated statement of shareholders' equity (deficit) for the years ended December 31, 2002 through December 31, 2011, incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2013 have been so included in reliance on the report of PricewaterhouseCoopers LLP (Canada), an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

MARKET AND INDUSTRY DATA

Unless otherwise indicated, information contained in this prospectus concerning the pharmaceutical industry, including our market opportunity, is based on information from independent industry analysts, third-party sources and management estimates. Management estimates are derived from publicly-available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on assumptions made by us based on such data and our knowledge of such industry and market, which we believe to be reasonable. In addition, while we believe the market opportunity information included in this prospectus is generally reliable and is based on reasonable assumptions, such data involves risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "Risk Factors."

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the common shares being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common shares offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at *http://www.sec.gov*. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street NE, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at 1258 Prospect Street, La Jolla, California 92037 or telephoning us at (858) 777-1760.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" certain of our publicly-filed documents into this prospectus, which means that information included in those documents is considered part of this prospectus. We incorporate by reference the documents listed below.

The following documents filed with the SEC are incorporated by reference in this prospectus:

our Annual Report on Form 10-K for the year ended December 31, 2013 (other than information furnished rather than filed), filed with the SEC on March 14, 2014;

Table Of Contents

our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 (other than information furnished rather than filed), filed with the SEC on May 13, 2014;

our Current Reports on Form 8-K, filed with the SEC on January 31, 2014, February 6, 2014, February 18, 2014, March 25, 2014, March 27, 2014, May 19, 2014 and June 2, 2014 (other than portions of those documents not deemed to be filed);

the portions of our Definitive Proxy Statement on Schedule 14A filed on April 7, 2014 that are deemed “filed” with the SEC; and

the description of our common shares in our Registration Statement on Form 8-A (File No. 333-186724) filed on August 9, 2013, including any amendment or reports filed for the purpose of updating this description.

You may access our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Proxy Statement, Current Reports on Form 8-K and amendments to any of these reports, free of charge on the SEC’s website. You may also access the documents incorporated by reference on our website at www.optimerpharma.com. We do not consider information contained on, or that can be accessed through, our website to be part of this prospectus.

In addition, we will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference. You should direct any requests for documents to Corporate Secretary, 1258 Prospect Street, La Jolla, California, 92037 or call (858) 777-1760.

Table Of Contents

SOPHIRIS BIO, INC.

CONSOLIDATED FINANCIAL STATEMENTS

Please see Item 15 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed with the Securities and Exchange Commission on March 14, 2014, and Item 1 in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, filed with the Securities and Exchange Commission on May 13, 2014, which are incorporated herein by reference, for our consolidated financial statements.

Table Of Contents

3,409,629 Shares

Common Shares

PROSPECTUS

June 23, 2014