SOPHIRIS BIO INC.
Form 424B7
May 06, 2015
**Filed Pursuant to Rule 424(b)(7)**

**Registration No. 333-196331**

**PROSPECTUS**

**3,409,629 Shares**

**Sophiris Bio Inc.**

**Common Shares**

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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 April 23, 2015, the last reported sale price per common share was $0.83 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.

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**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 May 6, 2015

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**TABLE OF CONTENTS**



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**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

**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.

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 an early 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.
- 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.

**The Offering**

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|---|---|
| **Common shares being offered by the selling shareholder** | 3,409,629 shares |
| **Common shares outstanding** | 16,844,736 (as of April 24, 2015) |
| **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 to 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 April 24, 2015, there were 16,149,871 of our common shares outstanding 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. 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 after this registration statement is declared effective under the Securities Act, 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.

After the Securities and Exchange Commission has declared effective the registration statement of which this prospectus is a part, 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 $1.0 million 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. The closing sale price of our common shares has not exceeded $2.00 at any time in the period of January 1, 2015 to April [24], 2015.

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;

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.

In connection with entering into the Purchase Agreement, we authorized the sale to Aspire Capital of up to $15.0 million of our common shares. 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 common shares 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) |
|---|---|---|---|
| $2.50 | $8.3 | 3.3 | 16% |
| $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% |

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

(2) The denominator is based on 16,844,736 shares outstanding as of April 24, 2015, 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.

## RISK FACTORS

*Investing in our common shares involves a high degree of risk. Before making an investment decision, you should carefully consider the risk factors described in our Annual Report on Form 10-K, filed with the SEC on March 10, 2015, which is incorporated by reference in this prospectus, and the other information contained or incorporated by reference in this prospectus. The risks and uncertainties incorporated by reference are not the only risks we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may impair our future business operations. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. In such case, the trading price of our common shares could decline and you could lose all or part of your investment.*

### 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 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 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 the Purchase Agreement. 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. However, as of April 24, 2015, we are not able to elect to sell any of the remaining shares under the Purchase Agreement as the closing price of our common shares does not exceed the floor price of $2.00 per share. 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.

6

**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 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; 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.

**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.

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

Please see Item 7 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the Securities and Exchange Commission on March 10, 2015, which is incorporated herein by reference, for a discussion of our financial condition and results of operations.

**BUSINESS**

**Overview**

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 the NASDAQ. We are currently developing PRX302 as a treatment for the lower urinary tract symptoms of benign prostatic hyperplasia, or BPH, commonly referred to as an enlarged prostate and as a treatment for localized low to intermediate risk prostate cancer. 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, which was completed in 2010, 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 Phase 3 clinical trial, which we often refer to as the “PLUS-1” trial, of PRX302 for the treatment of the lower urinary tract symptoms of BPH. We completed enrollment of 479 patients in the PLUS-1 study in September 2014 and expect to have final results of the trial in the fourth quarter of 2015. This Phase 3 clinical trial uses the International Prostate Symptom Score, or IPSS, outcome measure evaluated over 52 weeks as the primary endpoint. Secondary endpoints include Qmax (maximum urine flow) change from baseline over 52 weeks.

In December 2014, the Independent Data Monitoring Committee, or IDMC, completed a planned, protocol-specified administrative interim analysis of efficacy based on the IPSS change from baseline to Week 12 for all 479 patients dosed in the PLUS-1 trial. The protocol-specified administrative interim analysis of efficacy set a threshold at 12 weeks defined as an IPSS treatment effect of ≥ 2.0 points favoring PRX302 over vehicle-only (i.e. average IPSS total score change from baseline (CFB) for PRX302 minus IPSS CFB for vehicle-only). The IDMC reported that the predefined efficacy threshold at week 12 was not achieved. This administrative interim analysis was conducted specifically for planning subsequent clinical trials. The ongoing PLUS-1 trial is unaffected by this recommendation, and all patients in the trial will continue to be followed to enable the evaluation of the primary efficacy endpoint at 52 weeks. Simultaneously with this administrative interim efficacy analysis, the IDMC completed its fifth and final periodic analysis of unblinded safety data and reported no safety concerns. There were no events of sepsis reported post administration of PRX302 in this trial. The company and its representatives have remained blinded to the results

of this administrative analysis and will continue to remain blinded throughout the duration of the study until after the database is locked at the conclusion of the 52 week trial. In order to seek regulatory approval for PRX302 for the treatment of the symptoms of BPH, we would be required to conduct a second Phase 3 clinical trial and we do not expect to commence any additional Phase 3 clinical trials without receiving favorable results from the PLUS-1 trial and unless we raise the additional funds required to conduct the second Phase 3 clinical trial.

We plan to initiate a Phase 2 proof of concept trial of PRX302 for the treatment of localized low to intermediate risk prostate cancer prior to the end of the first half of 2015. The study will be conducted at a single center and enroll approximately 20 patients who have not been previously treated for their prostate cancer. Patients will receive a transperineal administration of PRX302 under general anesthesia at a dose higher than used in the ongoing BPH PLUS-1 trial but less than the highest dose used in our previous prostate cancer trial. The primary objective of the trial will be to assess the safety and tolerability of PRX302 when used to selectively target and focally ablate a clinically significant lesion. The potential efficacy will be evidenced by histological and MRI changes, indicating tumor control at six months. If tumor control is observed, we believe that PRX302 could offer a potential to provide a focal, targeted therapy for the ablation of localized prostate cancer while potentially avoiding many of the complications and side effects associated with radical treatments. Any potential efficacy signal would have to be confirmed in larger clinical studies. 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 targeting and ablating tumors in the prostate. In 2004, we licensed exclusive rights to PRX302 from UVIC and Johns Hopkins for the treatment of prostate cancer.

**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% 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 five 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.

***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 three 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 2 to 3 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.

*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 significantly improved 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 an 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.

**Background on Localized Low to Intermediate Risk Prostate Cancer**

Prostate cancer is the fourth leading cause of death due to cancer in the United States. As a result of an increase in life expectancy along with the current practice of formal and informal screening using prostate-specific antigen (PSA) blood tests, disease treatment has shifted towards early detection of low risk disease.

Each year approximately 230,000 new cases of prostate cancer in the United States are identified and more than one-third of patients are diagnosed with early disease. Research has shown that in many cases patients with early localized disease have a low likelihood of the cancer spreading beyond the confines of the prostate. Nevertheless, approximately 44% of the men with early disease choose to undergo radical treatment to address their disease. Radical therapies include surgery to remove the entire prostate and/or radiation. Potential toxicities from radical treatments can be significant and permanent and include erectile dysfunction, incontinence and rectal toxicity.

Men who do not elect radical therapy may undergo active surveillance, which does not offer any therapeutic benefit but does continue to monitor the patient (typically PSA levels, digital rectal exams and periodic or as indicated biopsies) for any progression of disease. The additional information is used to determine if a patient can remain in active surveillance or should undergo treatment. Once given the diagnosis of prostate cancer, the psychological impact on a man can be profound as is demonstrated by a significant proportion of men (about 10% in most studies) electing to undergo a radical treatment, even though they have had no evidence of biochemical or histopathological progression during their time in active surveillance.

**PRX302 for the Targeted Treatment of Localized Low to Intermediate Risk Prostate Cancer**

The intraprostatic injection of PRX302 represents a highly targeted investigational approach for potentially treating localized prostate cancer that is still confined within the encapsulated prostate gland for two reasons:

Focal targeted delivery of an intraprostatic injection to a tumor(s) within the prostate is now possible; and
PRX302 has a highly targeted mechanism of action, activated specifically only within the prostate tissue.

The increased use of multi-parametric magnetic resonance imaging (mpMRI) and advances in mapping previously obtained mpMRI images with live 3D ultrasound images also means that physicians are now able to locate tumors within the prostate and take more accurate biopsies, increasing the diagnosis of clinically significant lesions. These technical advances are enabling physicians and patients to make a more informed decision about whether to undergo radical treatment or active surveillance. In addition, these advances enable the injection of PRX302 directly into the tumors located within the prostate. The targeted focal treatment of early prostate cancer is in line with the treatment approach being used for other solid tumors such as breast or liver cancer, where the goal is to remove the tumor and preserve as much of the organ as possible.

The mechanism of action of PRX302 allows for a highly targeted therapeutic activity in localized disease. PRX302 is only activated in the presence of enzymatically active PSA which is found surrounding prostate cancer lesions. Therefore, we believe PRX302 has the potential to provide a focal targeted therapy for the ablation of localized prostate cancer while potentially avoiding many of the complications and side effects associated with radical treatments.

***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 PSA (as shown in the figure below), an enzyme that is produced in large quantities in the prostate of men with BPH and prostate cancer.

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. 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**

***Clinical Overview***

To date, we have completed six clinical trials of PRX302 and we have completed enrollment in our on-going Phase 3 clinical trial, PLUS-1, for the treatment of the lower urinary tract symptoms of BPH. Four completed clinical trials were for the treatment of the symptoms of BPH and two were for the treatment of prostate cancer. From the 6 completed clinical trials and the ongoing PLUS-1 clinical trial an estimated total of 366 patients with moderate to severe BPH and 30 patients with prostate cancer have been treated with PRX302 for an estimated combined PRX302 exposure of 396 patients.

Each of the clinical trials administered PRX302 as a single intraprostatic administration with 12 months of follow up. To date, no patients have been administered more than one exposure to PRX302. The first five trials for PRX302 (two prostate cancer trials and three BPH trials) used the transperineal route of administration for the intraprostatic injection and the two most recent clinical trials in BPH, including our on-going PLUS-1 trial, used the transrectal route. The transrectal route appears to be as well tolerated as the transperineal route and is more familiar to urologists.

All of the completed clinical trials of PRX302 for the treatment of the symptoms of BPH have 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 trials 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 PRX302 injection. There were no drug-related erectile dysfunction or cardiovascular side effects reported.

In order to seek regulatory approval for PRX302 for the treatment of the symptoms of BPH, we would be required to conduct a second Phase 3 clinical trial and we do not expect to commence any additional Phase 3 clinical trials without receiving favorable results from the PLUS-1 trial and unless we raise the additional funds required to conduct the second Phase 3 clinical trial.

15

*Clinical Development in BPH*

Our clinical program for PRX302 is summarized below.

*Completed Clinical Development in BPH*

| CLINICAL TRIAL | STATUS | TRIAL DESIGN |
|---|---|---|
| **PRX302-2-03**<br>**TRIUMPH**<br>Phase 2b | Completed | Randomized, double-blinded, placebo-controlled trial of a single transperineal intraprostatic treatment of PRX302<br>92 patients; 61 on PRX302; 31 on placebo<br>Dosing: 0.6 µg/g<br>Volume: 20% of prostate volume |
| **PRX302-2-06**<br>**Transrectal Study**<br>Phase 1/2 | Completed | Randomized dose-escalation, multicenter trial of a single transrectal intraprostatic treatment of PRX302<br>40 patients; 32 on PRX302 in 4 dosing cohorts; 8 on placebo<br>Dosing: 0.15µg/g, 0.30µg/g, 0.60µg/g, 1.2µg/g<br>Volume: 20% of prostate volume |
| **PRX302-2-02**<br>Phase 2a | Completed | Open-label, safety, volume escalation clinical trial of a single transperineal intraprostatic treatment of PRX302<br>18 patients<br>Dosing: 0.3µg/g, 0.6µg/g, 0.9µg/g<br>Volume: 10 to 30% of prostate volume |
| **PRX302-2-01**<br>Phase 1 | Completed | Open-label, safety, dose-escalation clinical trial of a single transperineal intraprostatic treatment of PRX302<br>15 patients<br>Dosing: 0.025µg/g, 0.072µg/g, 0.25µg/g, 0.35µg/g<br>Volume: 1.5 to 2.0 mL |

*Ongoing and Planned Clinical Development in BPH and Localized Prostate Cancer*

| CLINICAL TRIAL | STATUS | TRIAL DESIGN |
|---|---|---|
| **PLUS-1** | | 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 |
| Phase 3 Trial #1 for the treatment of the symptoms of BPH | On-going/Enrollment Completed | 479 patients<br><br>Dosing: 0.6µg/g<br><br>Volume: 20% of prostate volume |
| Phase 2 Safety Trial for the treatment of localized low to intermediate risk prostate cancer | Anticipated initiation of enrollment by the end of the first half 2015 | Phase 2 proof of concept study with PRX302 in patients who have localized low to intermediate risk prostate cancer. The study will be conducted at a single center and enroll approximately 20 patients. The primary objective will be to assess the safety and tolerability of PRX302 when used to selectively target and focally ablate a clinically significant lesion.<br><br>20 patients<br><br>Dosing: Will vary based upon prostate volume and the size of the lesion to be injected but the dose will not exceed 5µg/g |
| Phase 3 Trial #2 for the treatment of the symptoms of BPH | Planned but initiation dependent upon 12 months results from the PLUS-1 trial | Prospective, randomized, double-blind, placebo-controlled clinical trial of a single transrectal intraprostatic treatment of PRX302<br><br>Dosing: TBD<br><br>Volume: 20% of prostate volume |
| Open-Label Safety Study<br><br>Phase 3 for the treatment of the symptoms of BPH | Planned but initiation dependent upon 12 months results from the PLUS-1 trial | Safety of repeat dose and long-term safety of transrectal intraprostatic treatment of PRX302<br><br>Approximately 100 patients<br><br>Dosing: TBD<br><br>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 Phase 3 clinical trial, which we often refer to as the “PLUS-1” trial, of PRX302 for the treatment of the lower urinary tract symptoms of BPH. We completed enrollment of 479 patients in the PLUS-1 trial in September 2014 and expect to have final results of the trial in the fourth quarter of 2015. This multicenter, multinational clinical trial randomized patients across approximately 90 clinical trial sites to one of two treatment groups. This Phase 3 clinical trial uses the IPSS outcome measure evaluated over 12 months as the primary endpoint. This Phase 3 clinical trial is a randomized, double-blind, 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.

In December 2014, the IDMC for the PLUS-1 trial conducted a planned, protocol-specified administrative interim analysis of efficacy once all patients had completed three months of treatment. The IDMC completed the administrative analysis of efficacy based on the IPSS change from baseline to Week 12 for all 479 patients dosed in the PLUS-1 trial. The protocol-specified administrative interim analysis of efficacy set a threshold at 12 weeks defined as an IPSS treatment effect of ≥ 2.0 points favoring PRX302 over vehicle-only (i.e. average IPSS total score change from baseline (CFB) for PRX302 minus IPSS CFB for vehicle-only). The IDMC reported that the predefined efficacy threshold at week 12 was not achieved. This administrative interim analysis was conducted specifically for planning subsequent clinical trials. The ongoing PLUS-1 trial is unaffected by this recommendation, and all patients in the trial will continue to be followed to enable the evaluation of the primary efficacy endpoint at 52 weeks. Simultaneously with this administrative interim efficacy analysis, the IDMC completed its fifth and final periodic analysis of unblinded safety data and reported no safety concerns. There were no events of sepsis reported post administration of PRX302 in this trial. The company and its representatives have remained blinded to the results of this administrative analysis and will continue to remain blinded throughout the duration of the trial until after the database is locked at the conclusion of the 52 week trial.

In order to seek regulatory approval for PRX302 for the treatment of the symptoms of BPH, we would be required to conduct a second Phase 3 clinical trial and we do not expect to commence any additional Phase 3 clinical trials without receiving favorable results from the PLUS-1 trial and unless we raise the additional funds required to conduct the second Phase 3 clinical trial.

***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 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.
- *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

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.

***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***

We will need to complete a second Phase 3 clinical trial of PRX302 for the treatment of the symptoms of BPH which would be initiated after the completion of our on-going PLUS-1 trial. We will need to raise additional capital resources to fund this second Phase 3 clinical trial.

To date, no patients have been administered more than one treatment of PRX302. Assuming sufficient capital resources and assuming a successful outcome from our on-going PLUS-1 trial, we are planning to initiate an open label repeat dose clinical trial 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 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.

*Clinical Development in Prostate Cancer*

***Planned Clinical Development***

We plan to initiate a Phase 2 proof of concept clinical trial with PRX302 in patients who have localized low to intermediate risk prostate cancer before the end of the first half of 2015. The study will utilize previously obtained multi-parametric magnetic resonance imaging (mpMRI) mapped to real time 3D ultrasound to target the delivery of PRX302 directly into and around a pre-identified clinically significant tumor. The study will be conducted at a single center and enroll approximately 20 patients that have not been previously treated for their prostate cancer. In this proof of concept trial, patients will receive a transperineal administration of PRX302 at a dose higher than used in the ongoing BPH PLUS-1 study but less than the highest dose used in our previous prostate cancer trials. The primary objective will be to assess the safety and tolerability of PRX302 when used to selectively target and focally ablate a clinically significant lesion. The potential efficacy will be evidenced by histological and MRI changes in the tumor at six months.

***Completed Clinical Development***

***Phase 2 Open-Label Clinical Trial in Prostate Cancer***

In September 2009, we completed a Phase 2 clinical trial of PRX302 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.

***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.

**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 complete our ongoing Phase 3 clinical trial for BPH in the fourth quarter of 2015. Depending on the outcome of the Phase 3 clinical trial, we may seek a development partnership to fund the second Phase 3 clinical trial that would be required to seek regulatory approval, based on feedback from the FDA and European regulatory agencies.
- *Initiate and complete a proof of concept study of PRX302 for the treatment of localized low to intermediate risk prostate cancer.* We plan to initiate a Phase 2 proof of concept study with PRX302 in patients who have localized low to intermediate risk prostate cancer by the end of the first half of 2015. The study will be conducted at a single center and enroll approximately 20 patients. The primary objective will be to assess the safety and tolerability of PRX302 when used to selectively target and focally ablate a clinically significant lesion. The potential efficacy will be evidenced by histological and MRI changes, indicating tumor control at six months. If the outcome of the proof of concept study is successful, we intend to pursue additional clinical development of PRX302 as a focal prostate cancer treatment.
- *Maximize the commercial potential of PRX302*. If we obtain marketing approval of PRX302 for the treatment of the symptoms of BPH and/or the treatment of localized low to intermediate risk prostate cancer, 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.

In addition, there are other treatments that are currently in clinical development for the treatment of the symptoms of BPH. Light Sciences Oncology Inc.'s Aptocine™ is currently in Phase 2 clinical trials. In 2014, Nymox Pharmaceuticals announced that the injectable NX-1207 for the treatment of the symptoms of BPH did not meet its clinical endpoints in two completed Phase 3 clinical trials and we do not know that status of future development of NX-1207.

We expect that PRX302 will complete with the current treatment options for the treatment of localized low to intermediate risk prostate cancer, which include surgical options such as laparoscopic and radical prostatectomy or radiation. In addition, there are other focal targeted therapies which are gaining traction that are currently in clinical development or have been recently approved which include: brachytherapy, cryotherapy, high frequency ultrasound, cyber knife, radio frequency ablation and laser ablation.

**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 2012, 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 scale-up up to the commercial batch size for drug substance. The finalization of the commercial fill finish process, for the production of drug product is still underway but the commercial fill finish process may be subject to change based upon regulatory feedback. 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. Further, BI currently procures an ingredient used in the formulation of PRX302 from a multinational industrial biotech company which is a single source supplier.

***Supply Agreement with 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 have been 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.

**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 four 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 six issued United States patents related to our prostate program: US 7,838,266 (prostate cancer) expiring in 2022, US 7,282,476 (prostate cancer) expiring in 2023, US 7,745,395 (prostate cancer) expiring in 2023, US 8,278,279 prostatitis) expiring in 2029, US 8,901,070 (prostatitis) expiring in 2029 and US 8,916,161 (BPH) expiring in 2026, as well as six issued patents in countries including Australia, China, the European Patent Office (including 17 extension states), India, Japan, and South Africa expiring in 2022, nine 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 15 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, and methods 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 in July 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%.

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 a $5.0 million non-refundable milestone payment due from Kissei upon the achievement of certain development activities. 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.

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, 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;
- possible 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.

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.
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*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 goal 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.

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.

*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 Health Regulation 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. Because of the breadth of these laws and the narrowness of the applicable exceptions and safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

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 exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions 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 and civil monetary penalties laws prohibit, among other things, any person or entity 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.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit, among other things, 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, also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. In addition, many states have adopted laws similar to each of the above federal laws, such as anti-kickback and false claims laws, some of which may apply to items or services reimbursed by any third-party payor, including commercial insurers. We are also subject to 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.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal and civil and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, administrative burdens, diminished profits and future

earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In the United States and foreign jurisdictions, there have been and continue to be a number of initiatives that seek to reduce healthcare costs. For example, in March 2010 the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education 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;
- new requirements on certain manufacturers of drugs, devices, biological products and medical supplies to report annually certain financial arrangements, including reporting any “transfer of value” made or distributed to physicians and teaching hospitals and reporting annually certain ownership and 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 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.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and will stay in effect through 2024 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals and imaging centers.

We expect that additional state, federal and foreign healthcare reform measures will be adopted in the future, any of which could result in reduced demand for our products or other adverse effects.

*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 including government health administrative authorities, managed care providers, private health insurers and other organizations.

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the associated costs. 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 third-party payor reimbursement for the cost of our products and/or payment to the physician for administering our product.

**Employees**

As of December 31, 2014, we had nine full-time employees and one part-time employee, 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.

**Research and Development Expenses**

Research and development expenses consist primarily of costs associated with the clinical development of PRX302. Research and development expenses are the primary source of our expenses and totaled $24.7 million, $10.3 million and $13.5 million for the years ended December 31, 2014, 2013 and 2012, respectively.

**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."

**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.

## 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 24, 2015, 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 24, 2015, which is incorporated herein by reference.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2012 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.

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 24, 2015, 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."

**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.

**PRINCIPAL SHAREHOLDERS**

Please see the section entitled “Principal Shareholders” in our Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on April 24, 2015, which is incorporated herein by reference.

**DILUTION**

The sale of our common shares to Aspire Capital pursuant to the Purchase Agreement will have a dilutive impact on our shareholders. As a result, our net income per share, if any, would decrease in future periods and the market price of our common shares 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 common shares we will have to issue to Aspire Capital pursuant to the Purchase Agreement and our existing shareholders would experience greater dilution. As of December 31, 2014, we had a net tangible book value of $14.7 million, or approximately $0.87 per common share.

Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of common shares in this offering, assuming a purchase price of $2.00 per share, which is the minimum purchase price at which shares can be sold under the Purchase Agreement, and the pro forma as adjusted net tangible book value per common share immediately after the completion of this offering.

Of the 3,409,629 shares being offered hereunder, 694,865 shares were issued to Aspire Capital in 2014. Therefore, after giving effect to our assumed receipt of an additional $5.3 million in estimated net proceeds from the issuance of 2,714,764 additional common shares under the Purchase Agreement and registered in this offering (assuming a purchase price of $2.00 per share and assuming all such sales and issuances were made on December 31, 2014), our pro forma as adjusted net tangible book value as of December 31, 2014 would have been approximately $20.0 million, or $1.02 per share. This would represent an immediate increase in the net tangible book value of $0.15 per share to existing shareholders attributable to this offering. The following table illustrates this per share dilution:

| | |
|---|---|
| Assumed public offering price per common share (minimum allowed price) | $2.00 |
| As adjusted net tangible book value per share as of December 31, 2014 | 0.87 |
| Increase in as adjusted net tangible book value per share attributable to this offering | 0.15 |
| Pro forma net tangible book value per share after this offering | 1.02 |
| Dilution per share to new investors | $0.98 |

To the extent that we sell more or less than an additional $5.3 million worth of shares under the Purchase Agreement, or to the extent that some or all sales are made at prices in excess of the minimum allowable purchase price of $2.00 per share, then the dilution reflected in the table above will differ. The above table is based on 16.8 million common shares outstanding as of December 31, 2014, adjusted for the assumed sale of an additional $5.3 million in shares to Aspire Capital under the Purchase Agreement at the assumed minimum purchase price described above. In addition, the calculations in the foregoing table do not take into account, as of December 31, 2014: 1.4 million common shares issuable upon the exercise of outstanding options, with a weighted average exercise price of $6.65 per share; and 1.0 million common shares issuable upon the exercise of outstanding warrants, with a weighted average exercise price of $24.17 per share.

To the extent that options or warrants are exercised, new options are issued under our equity benefit plans, or we issue additional common shares in the future, there may be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

**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** | **%** |
| Aspire Capital Fund, LLC (2) | 694,865 (3) | 3,409,629 (3) | 0 | 0 % |

(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) 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.

(3) 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.

**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 24, 2015, 16,844,736 of our common shares were outstanding, held by 27 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, 20,254,365 of our common shares will be outstanding.

**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, 2012 through November 13, 2013, on the TSX, quoted in Canadian Dollars and August 16, 2013 through April 24, 2015 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$** | **CND$** |

| | | | | |
|---|---|---|---|---|
| **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 | 3.73 | 2.10 | — | — |
| Third Quarter | 3.34 | 2.23 | — | — |
| Forth Quarter | 3.25 | 0.42 | — | — |
| | | | | |
| **2015** | | | | |
| First Quarter | $1.04 | $0.42 | — | — |
| Second Quarter (through April 24, 2015) | 1.13 | 0.54 | — | — |

**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.

37

**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 24, 2015, there were 0.9 million common share purchase warrants outstanding, which expire between November 19, 2015 and June 2021. Each of these warrants entitles the holder to purchase one common share at prices ranging between $2.19 and $28.17 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.

*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 1.6 million common shares have been granted and are outstanding as of April 24, 2015 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.

**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.”

39

**Transfer Agent and Registrar**

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

**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.

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.

**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 incorporated in this Prospectus by reference to Sophiris Bio Inc.'s Current Report on Form 8-K dated April 27, 2015 have been so incorporated in reliance on the report (which contains a reference to Note 1 to the financial statements) of PricewaterhouseCoopers LLP, 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, 2014 (other than information furnished rather than filed), filed with the SEC on March 10, 2015;
- our Current Reports on Form 8-K, filed with the SEC on January 30, 2015, February 6, 2015 and April 27, 2015 (other than portions of those documents not deemed to be filed);
- the portions of our Definitive Proxy Statement on Schedule 14A filed on April 24, 2015 that are deemed "filed" with the SEC; and
- the description of our common shares in our Registration Statement on Form 8-A (File No. 001-36054) 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.sophiris.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.

**SOPHIRIS BIO, INC.**

**CONSOLIDATED FINANCIAL STATEMENTS**

Please see Exhibit 99.1 in our Current Report on Form 8-K for the fiscal year ended December 31, 2014, filed with the Securities and Exchange Commission on April 27, 2015, which is incorporated herein by reference, for our consolidated financial statements.

**3,409,629 Shares**

**Common Shares**

**PROSPECTUS**

**May 6, 2015**