SOPHIRIS BIO INC.
Form 424B4
August 16, 2013
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Filed Pursuant to Rule 424(b)(4)
Registration Statement No. 333-186724

PROSPECTUS

13,000,000 Shares

Sophiris Bio Inc.

Common Shares

US$5.00 per share

This is the initial U.S. public offering of our common shares. We have applied to list our common shares on the NASDAQ Global Market under the symbol SPHS. Our common shares are currently listed on the Toronto Stock Exchange under the symbol SHS. On August 14, 2013, the last reported sale price of our common shares on the Toronto Stock Exchange was CND$0.17 per share, or US$0.16 per share, or US$8.32 per share after giving effect to a share consolidation of our common shares which was effected on August 9, 2013. The initial public offering price of our common shares is US$5.00 per share.

We have granted the underwriters an option to purchase up to 1,950,000 additional common shares to cover over-allotments.

Investing in our common shares involves risks. See Risk Factors beginning on page 12.

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.

	Per Share	Total
Public Offering Price	US$ 5.00	US$ 65,000,000
Underwriting Discount (1)	US$ 0.35	US$ 4,550,000
Proceeds to Sophiris (before expenses)	US$ 4.65	US$ 60,450,000

(1) We refer you to Underwriting beginning on page 137 for additional information regarding underwriting compensation. Certain of our existing shareholders and their affiliated entities have agreed to purchase approximately $22.4 million of our common shares in this offering at the public offering price.

The underwriters expect to deliver the common shares to purchasers on or about August 23, 2013 through the book-entry facilities of The Depository Trust Company.

Citigroup **Leerink Swann**

Stifel **Lazard Capital Markets**

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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.

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SUMMARY

This summary highlights information contained in other parts of this prospectus that we consider important. This summary does not contain all of the information you should consider before investing in our common shares and it is qualified in its entirety by the more detailed information appearing elsewhere in this prospectus. You should read this summary together with the more detailed information appearing in this prospectus, including Risk Factors, Business and our consolidated financial statements and the related notes included at the end of this prospectus, before making an investment in our common shares. Unless the context otherwise requires, any reference to Sophiris, we, our, us and the company in this prospectus refers to Sophiris Bio Inc. and our subsidiaries, Sophiris Bio Corp., a Delaware corporation, and Sophiris Bio Holding Corp., a Delaware corporation. In this prospectus, unless otherwise specified, all monetary amounts are in U.S. dollars. All references in this prospectus to $, US$, dollars and USD mean U.S. dollars. Our consolidated financial statements are presented in U.S. dollars and all references to $ in our consolidated financial statements mean U.S. dollars. All references to Canadian dollars, and CND$ mean Canadian dollars.

SOPHIRIS BIO INC.

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 Toronto Stock Exchange. We are currently developing PRX302 as a treatment for the symptoms of benign prostatic hyperplasia, or BPH, commonly referred to as an enlarged prostate. Initially, most men with BPH will be treated with oral medications but many will discontinue drug therapy due to inadequate response and/or side effects, which include sexual dysfunction and cardiovascular side effects. They may then undergo a surgical procedure, which can be painful and have potential long-term sexual side effects, or may stop treatment altogether. PRX302 is designed to be a convenient treatment that is safer and less invasive than surgery and more effective and better tolerated than currently approved pharmaceutical therapies. In our Phase 2b clinical trial, we saw significant symptom relief from a single treatment of PRX302 that was sustained throughout the follow-up period of 12 months, and there were no drug-related erectile dysfunction or cardiovascular side effects reported. In 2009, we licensed exclusive rights to PRX302 from UVIC Industry Partnerships Inc., or UVIC, and The Johns Hopkins University, or Johns Hopkins, for the treatment of the symptoms of BPH. In April 2010, we entered into an exclusive license agreement with Kissei Pharmaceutical Co., Ltd., for the development and commercialization of PRX302 in Japan for the treatment of the symptoms of BPH, prostate cancer, prostatitis or other diseases of the prostate.

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

We expect to initiate in the second half of 2013 the first of two planned Phase 3 clinical trials of PRX302 for the treatment of the symptoms of BPH. Based on feedback from our guidance meeting with the FDA in February 2013, we expect to enroll approximately 440 patients in this Phase 3 clinical trial. This Phase 3 clinical trial will use the IPSS outcome measure evaluated at 12 months as the primary endpoint, which is consistent with clinical trials of another injectable currently under development for the treatment of the symptoms of BPH.

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Assuming sufficient capital resources, we plan to commence our second Phase 3 clinical trial following a blinded interim analysis conducted by an independent data monitoring committee once all patients have completed three months in the first Phase 3 clinical trial, which analysis we expect to occur by the end of 2014.

Background on BPH

BPH is a non-cancerous enlargement of the prostate gland that commonly affects men who are age 50 and older. BPH causes a restriction in urine flow from the urethra resulting in lower urinary tract symptoms, or LUTS. BPH, and its associated clinical manifestations of LUTS, is one of the most common medical conditions of aging men in the United States, with approximately 70% of men aged 60-69 years and 80% of men older than the age of 70 being affected by BPH. The number of men with symptoms of BPH is expected to increase as the male population ages. 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.

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 and clinical results to date suggest it is safer and better tolerated than existing therapies. It is delivered through a targeted injection into the prostate, precisely ablating the prostate tissue without damaging neighboring tissue and nerves. This method of administration limits the circulation of the drug in the body and we believe that this limited systemic exposure to the drug, together with how the drug is activated in the body, greatly diminishes the risk of side effects. In our Phase 2b clinical trial, PRX302 has been shown to significantly improve symptoms of BPH through 12 months of follow-up after a single treatment.

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

PRX302 Transrectal Administration Schematic

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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 minimally invasive surgical therapies, or MIST, such as transurethral needle ablation, or TUNA, and transurethral microwave thermotherapy, or TUMT. When compared to the more invasive transurethral resection of the prostate, or TURP, 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.

PRX302- Mechanism of Action

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

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

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The mechanism of action is shown in the figure below.

PRX302 Mechanism of Action

PRX302- Clinical Overview

To date, we have conducted six clinical trials of PRX302. Four of these clinical trials were for the treatment of the symptoms of BPH and two were for the treatment of prostate cancer. A total of 126 patients with moderate to severe BPH symptoms and 30 patients with prostate cancer have been treated with PRX302, for a combined PRX302 exposure of 156 patients. In each of the six trials, patients were monitored for 12 months following a single treatment of PRX302.

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

In clinical trials in patients with BPH, PRX302 has consistently shown clinically meaningful, sustained efficacy with regard to improvement in LUTS, as measured by the IPSS and improvement in peak urine flow rate, or Qmax, the standard measures of the treatment of symptoms for BPH. PRX302 has been well-tolerated in all clinical studies to date. Adverse events were typically mild and transient in nature, limited to local discomfort and irritative urinary symptoms that generally occur during the first four days after injection. There were no drug-related erectile dysfunction or cardiovascular side effects reported.

Plans for future clinical development

We expect to initiate in the second half of 2013 the first of two Phase 3 clinical trials of PRX302 for treatment of the symptoms of BPH, which trial we sometimes refer to as PLUS-1. Based on feedback from our guidance meeting with the FDA in February 2013, our plan is that the first Phase 3 clinical trial will be a

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prospective, randomized, double-blind, vehicle-controlled clinical trial to confirm the efficacy and safety of a single treatment of PRX302 transrectally administered in patients with moderate to severe LUTS due to BPH. This multicenter, multinational clinical trial will randomize approximately 440 patients across as many as 100 clinical trial sites to one of two treatment groups. The proposed primary endpoint is the change from baseline in IPSS, which is the outcome measure that has been used in previous clinical trials of PRX302 and for the regulatory approval of oral medications for treatment of the symptoms of BPH as well as MIST procedures.

Assuming sufficient capital resources, we intend to initiate the second Phase 3 clinical trial following a blinded interim analysis conducted by an independent data monitoring committee once all patients have completed three months in the first Phase 3 clinical trial. Assuming sufficient capital resources, we are planning to initiate an open label repeat dose clinical trial before the end of 2014, 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, 12 months after their first dose.

Our Strategy

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

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

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

Evaluate further development of PRX302 in prostate cancer. Our current development of PRX302 is focused on the treatment of the symptoms of BPH. We will continue to evaluate future development of PRX302 in prostate cancer.

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.

Risk Factors

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

we have no approved products and no product revenue to date, and we may never become profitable;

we have incurred significant operating losses since our inception, including an accumulated deficit of $76.5 million as of June 30, 2013, and anticipate that we will continue to incur losses for the foreseeable future;

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

our success is primarily dependent on the regulatory approval and commercialization of PRX302 because it is our only product candidate;

clinical development is a lengthy and expensive process with an uncertain outcome, and because the results of early clinical trials are not necessarily predictive of future results, PRX302 may not have favorable results in later clinical trials;

PRX302 is subject to extensive regulation, and we may not obtain regulatory approval for PRX302 from the FDA or foreign regulatory authorities;

we rely on third parties to conduct our clinical trials and to manufacture supply of PRX302, and we cannot be certain that they will successfully carry out their contractual duties or meet required timelines;

if we are unable to obtain or protect intellectual property rights related to PRX302, we may not be able to compete effectively in our market;

sales of a substantial number of our common shares in the public market by our existing shareholders, including our common shares currently listed on the Toronto Stock Exchange, could cause our share price to fall; and

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

Company 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.

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 web site is not part of this prospectus. We currently trade on the Toronto Stock Exchange under the ticker symbol SHS.

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.

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Emerging Growth Company

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common shares that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We refer to the Jumpstart Our Business Startups Act of 2012 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 in addition to any required unaudited interim financial statements with 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.

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THE OFFERING

Common shares we are offering	13,000,000 shares
Common shares to be outstanding after this offering	16,149,869 shares
Over-allotment option	We have granted the underwriters an option for a period of up to 30 days to purchase up to 1,950,000 additional common shares at the initial public offering price.
Use of proceeds	We intend to use the net proceeds from this offering of approximately $57.0 million to fund the clinical development of PRX302, to make monthly principal and interest payments on our term loan with Oxford Finance LLC, and for general corporate purposes. See Use of Proceeds on page 46.
Risk factors	You should read the Risk Factors section of this prospectus beginning on page 12 for a discussion of the factors to consider carefully before deciding to invest in any of our common shares.
Proposed NASDAQ Global Market symbol	SPHS
Toronto Stock Exchange symbol	SHS

The number of common shares to be outstanding after this offering is based on 3,149,869 common shares outstanding as of June 30, 2013, as adjusted to reflect the 52-for-1 share consolidation of our common shares which was effected on August 9, 2013 and the 13,000,000 common shares included in this offering, and excludes:

- 300,590 common shares issuable upon the exercise of options outstanding as of June 30, 2013 pursuant to our stock option plan, at a weighted-average exercise price of CND$20.80 per share, or $19.78 per share, as converted, as adjusted to reflect the 52-for-1 share consolidation;
- 14,376 common shares available for future issuance under our stock option plan as of June 30, 2013, as adjusted to reflect the 52-for-1 share consolidation; and
- 918,868 common shares issuable upon the exercise of warrants outstanding as of June 30, 2013, at a weighted-average exercise price of CND$27.04 per share, or $25.71 per share, as converted, as adjusted to reflect the 52-for-1 share consolidation.

Except as otherwise noted, all information in this prospectus:

- gives effect to the 52-for-1 share consolidation of our common shares;

assumes no exercise by the underwriters of their option to purchase up to 1,950,000 additional common shares from us to cover over-allotments; and

with respect to financial measures, is presented in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. Certain of our existing shareholders and their affiliated entities, including entities affiliated with Tavistock Life Sciences Co., have agreed to purchase approximately $22.4 million of our common shares in this offering at the public offering price.

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We were required, pursuant to the policies of the Toronto Stock Exchange, to obtain shareholder approval for the terms of this offering, due to the fact that the public offering price of $5.00 per share represents a discount to the last reported sale price of our common shares on the Toronto Stock Exchange on August 14, 2013 that is greater than the maximum allowable discount under Section 607(e) of the Toronto Stock Exchange Issuer Manual. We have obtained shareholder approval by the written consent of more than 50% of the holders of our issued and outstanding shares.

Except as otherwise noted, all amounts referred to in this prospectus as $, as converted shall mean the U.S. dollar amount applying the conversion rate from Canadian dollars as of June 30, 2013.

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SUMMARY CONSOLIDATED FINANCIAL DATA

The following table summarizes our consolidated financial data. We derived the summary consolidated statement of operations data for the years ended December 31, 2011 and 2012 from our audited consolidated financial statements and related notes appearing elsewhere in this prospectus. We derived the summary consolidated statement of operations data for the six months ended June 30, 2012 and 2013 and the summary consolidated balance sheet data as of June 30, 2013 from our unaudited consolidated interim financial statements and related notes appearing elsewhere in this prospectus. The unaudited consolidated interim financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to fairly state our financial position as of June 30, 2013 and results of operations for the six months ended June 30, 2012 and 2013. Our historical results are not necessarily indicative of the results that may be achieved in the future and results of interim periods are not necessarily indicative of the results for the entire year. The summary consolidated financial data should be read together with our consolidated financial statements and related notes, and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus. Our audited consolidated annual financial statements and unaudited consolidated interim financial statements have been prepared in U.S. dollars in accordance with U.S. GAAP.

	Years ended December 31,		Six months ended June 30,	
	2011	2012	2012	2013
			(unaudited)	
	(in thousands, except per share data)			
Consolidated Statement of Operations Data:				
Revenues:	$	$	$	$ 5,000
Operating expenses:				
Research and development	8,660	13,523	6,783	4,025
General and administrative	4,635	5,685	2,362	2,126
Total operating expenses	13,295	19,208	9,145	6,151
Other income (expense)				
Interest income (expense), net	(895)	(1,880)	(1,004)	(751)
Other income (expense), net	(11)	(106)	(84)	(356)
Total other income (expense)	(906)	(1,986)	(1,088)	(1,107)
Net income (loss) before income tax expense	(14,201)	(21,194)	(10,233)	(2,258)
Income tax expense				(500)
Net loss	$ (14,201)	$ (21,194)	$ (10,233)	$ (2,758)
Basic and diluted net loss per common share[1][2]	$ (6.05)	$ (6.94)	$ (3.46)	$ (0.88)
Shares used to calculate net loss per common share[1][2]	2,345	3,054	2,956	3,150

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

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

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	As of June 30, 2013	
	Actual	Pro Forma As Adjusted[(1)] (unaudited)
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 3,570	$ 60,520
Working capital (deficit)	(3,991)	52,959
Total assets	6,348	63,298
Promissory notes, including current portion	9,351	9,351
Accumulated deficit	(76,456)	(76,456)
Total shareholders equity (deficit)	(7,039)	49,911

(1) Pro forma as adjusted reflects the sale of 13,000,000 common shares in this offering at the initial public offering price of $5.00 per share and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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RISK FACTORS

Investing in our common shares involves a high degree of risk. You should consider carefully the risks described below, together with all of the other information included in this prospectus, before deciding whether to invest in our common shares. The risks described below are material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually materialize, our business, prospects, financial condition, and results of operations could be seriously harmed. This could cause the trading price of our common shares to decline, resulting in a loss of all or part of your investment.

Risks Related to Our Business and Industry

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

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

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

To date, we have expended significant time, resources and effort on the development of PRX302, including conducting preclinical and clinical trials, for the treatment of the symptoms of BPH. We have no product candidates in our clinical development pipeline other than PRX302. Our ability to generate product revenues and to achieve commercial success in the near term will initially depend almost entirely on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize PRX302 in the United States and the European Economic Area, or EEA. Before we can market and sell PRX302 in the United States or foreign jurisdictions, we will need to commence and complete additional clinical trials, manage clinical, preclinical, and manufacturing activities, obtain necessary regulatory approvals from the Food and Drug Administration, or FDA, in the United States and from similar foreign regulatory agencies in other jurisdictions, obtain manufacturing supply, build a commercial organization or enter into a marketing collaboration with a third party, and in some jurisdictions, obtain reimbursement authorization, among other things. We cannot assure you that we will be able to successfully complete the necessary preclinical studies and clinical trials and/or obtain regulatory approvals and sufficient commercial manufacturing supply for PRX302. If we do not receive regulatory approvals, our business, prospects, financial condition and results of operations will be adversely affected. Even if we obtain regulatory approvals, we may never generate significant revenues from any commercial sales of PRX302. If we fail to successfully commercialize PRX302, we may be unable to generate sufficient revenues to sustain and grow our business and our business, prospects, financial condition and results of operations will be adversely affected.

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

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing and distribution and other possible activities relating to our product candidate are, and for any other biologic or drug candidate that we may develop will be, subject to extensive regulation by the FDA in the United States and other regulatory agencies in foreign jurisdictions. PRX302, our only product candidate, is subject to regulation in the United States as a biologic. Biologics require the submission of a Biologics License Application, or BLA, and we are not permitted to market PRX302 in the United States until we obtain approval from the FDA of a BLA. To market PRX302 in the EEA, which includes

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the 27 member states of the European Union plus Norway, Liechtenstein and Iceland, we must submit a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, for approval under the EMA s centralized procedure, which if the marketing authorization is granted, will enable us to market the product throughout the entire territory of the EEA. A BLA or MAA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, sufficient to demonstrate the safety and effectiveness of the applicable product candidate to the satisfaction of FDA and EMA, respectively.

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

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

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

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

- warning letters;
- civil and criminal penalties;

injunctions;

withdrawal of approved products;

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product seizure or detention;

product recalls;

total or partial suspension of production; and

refusal to approve pending BLAs or supplements to approved BLAs.

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

To market any biologics outside of the United States, we and current or future collaborators must comply with numerous and varying regulatory and compliance related requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement and pricing approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others, including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed. Certain countries have a very difficult reimbursement environment and we may not obtain reimbursement or pricing approval, if required, in all countries where we expect to market a product, or we may obtain reimbursement approval at a level that would make marketing a product in certain countries not viable.

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

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

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

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

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

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

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

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

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

Undesirable side effects caused by PRX302 could cause us or regulatory authorities to interrupt, delay, suspend or terminate clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other regulatory authorities. This, in turn, could limit or prevent us from commercializing PRX302 and generating revenues from its sale. To date, the most common adverse events observed in patients who received PRX302 in our Phase 2 clinical trials that were potentially attributable to PRX302 included the presence of red blood cells in urine, painful urination, frequent urination and urinary urgency, perineal pain and discomfort (observed in patients who received both drug and placebo, which is otherwise referred to as the vehicle), vertigo and malaise that could be attributable to PRX302 induced inflammation. Each of the foregoing adverse events occurred in greater than five percent of the PRX302 population. Although none of the patients in our Phase 1/2 clinical trial using the transrectal route of administration experienced sepsis, our change to this route of administration is expected to increase the risk of sepsis. Results from our planned Phase 3 clinical trials could reveal a high and unacceptable severity and

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prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of PRX302 for its targeted indication. Further, such side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may have a material and adverse impact on our business, prospects, financial condition and results of operations.

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

- regulatory authorities may withdraw their approval of PRX302;
- regulatory authorities may require that we demonstrate a larger clinical benefit by conducting additional clinical trials for approval to offset the risk;
- regulatory authorities may require the addition of labeling statements or warnings that could diminish the usage of the product or otherwise limit the commercial success of PRX302;
- we may be required to change the way PRX302 is administered;
- we may choose to recall, withdraw or discontinue sale of PRX302;
- we could be sued and held liable for harm caused to patients;
- we may not be able to enter into collaboration agreements on acceptable terms and execute on our business model; and
- our reputation may suffer.

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

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

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

- raising sufficient capital to fund the planned Phase 3 clinical trials;
- obtaining regulatory approval, or feedback on trial design necessary, to commence a clinical trial;

identifying, recruiting and training suitable clinical investigators;

identifying, recruiting and enrolling suitable patients to participate in a clinical trial;

catastrophic loss of drug product due to shipping delays or delays in customs in connection with delivery of drug product to foreign countries for use in clinical trials;

reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;

obtaining sufficient quantities of PRX302 for use in clinical trials;

having patients complete a trial or return for post-treatment follow-up;

adding new clinical trial sites;

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failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions;

unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;

obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site; and

retaining patients who have initiated a clinical trial but may withdraw due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues.

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

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

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

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

We do not plan to enter into an agreement with a CRO for our planned Phase 3 clinical trials of PRX302 until we have sufficient capital to fund our first planned Phase 3 clinical trial. We also rely upon medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and in accordance with applicable legal and regulatory requirements. These third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. There is no guarantee that any such third party will devote adequate time and resources to our clinical trial. If any of our CROs or any other third parties upon which we rely for administration and conduct of our clinical trials do not successfully carry out their contractual duties or obligations or fail to meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the

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failure to adhere to our clinical protocols or regulatory requirements or if they otherwise perform in a substandard manner, our clinical trials may be extended, delayed, suspended or terminated, and we may not be able to complete development of and ultimately obtain approval for and successfully commercialize PRX302. We will rely heavily on these third parties for the execution of our planned Phase 3 clinical trials and will control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities.

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

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

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

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

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

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

Our predecessor, Protox Pharmaceuticals Inc., was incorporated in January 2002. We were formed in May 2003 under the predecessor to the British Columbia Business Corporations Act, or the BCBCA, by the

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amalgamation of Stratos Biotechnologies Inc., Nucleus BioScience Inc. and Brightwave Ventures Inc. under the name SNB Capital Corp. In July 2004, we acquired all the shares of Protox Pharmaceuticals Inc. in a plan of arrangement under the BCBCA and changed its name to Protox Therapeutics Inc. In 2011, we formed a wholly-owned U.S. subsidiary incorporated in Delaware, Protox Therapeutics Corp. In 2012, we changed our name to Sophiris Bio Inc. and changed the name of our subsidiary to Sophiris Bio Corp. In 2012, Sophiris Bio Corp. formed a wholly-owned subsidiary incorporated in Delaware, Sophiris Bio Holding Corp. We face considerable risks and difficulties as a company with limited operating history, particularly as a consolidated entity with an operating subsidiary that also has a limited operating history. If we do not successfully address these risks, our business, prospects, operating results and financial condition will be materially and adversely harmed. Our limited operating history makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected. We are also subject to additional risks in connection with our recent relocation of our operations to San Diego, California and our recent hire of new members of our management team. Moreover, we do not have a product approved for commercial sale. We have limited experience as a consolidated operating entity, and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical or biotechnology areas.

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

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

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

The availability and price of our competitors products and procedures could limit the demand, and the price we are able to charge, for PRX302. We will not successfully execute on our business objectives if the market acceptance of PRX302 is inhibited by price competition, if physicians are reluctant to switch from existing

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products or procedures to PRX302, or if physicians switch to other new products or surgeries or choose to reserve PRX302 for use in limited patient populations. In addition, established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license and develop novel compounds that could make PRX302 obsolete.

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

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

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

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

Any regulatory approvals that we obtain for our product candidate may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable foreign regulatory authority, like the EMA, approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs for marketed drugs and drugs used in clinical trials and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product,

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including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

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

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

As of August 1, 2013, we had eight full-time employees and one part-time employee. In addition, we have engaged part-time individual consultants to assist us with establishing accounting systems, managing vendors and CROs, project management, regulatory compliance and business development. We will need to expand our managerial, operational, financial and other resources in order to manage our operations and clinical trials, continue our research and development activities, and commercialize our product candidate. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth. Our need to effectively manage our operations, growth and various projects requires that we:

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

To date, we have utilized the services of third-party vendors to perform tasks including clinical trial management, statistics and analysis, regulatory affairs, formulation development and other drug development functions. Our growth strategy may also entail expanding our group of contractors or consultants to implement these tasks going forward. Because we rely on numerous consultants, effectively outsourcing many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated,

and we may not be able to obtain regulatory approval for our product candidate or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may be unable to successfully implement the tasks necessary to further develop and commercialize our product candidate and, accordingly, may not achieve our research, development and commercialization goals.

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

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

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

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

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture PRX302 on a clinical or commercial scale. Instead, we rely on our third-party manufacturing partner, Boehringer Ingleheim RCV GmbH & Co KG, or BI, located in Austria, for the production of PRX302 and BI Germany for fill and testing services pursuant to an agreement which we entered into in 2011. The facilities used by our third-party manufacturer to manufacture PRX302 and any other potential product candidates that we may develop in the future must be approved by the applicable regulatory authorities, including the FDA, pursuant to inspections that will be conducted after we submit our BLA to the FDA. We do not control the manufacturing processes of BI and are currently completely dependent on BI for the production of PRX302 in accordance with cGMPs, which include, among other things, quality control, quality assurance and the maintenance of records and documentation.

Although we have entered into an agreement for the manufacture of clinical supplies and initial commercial supplies of PRX302, BI may not perform as agreed, may be unable to comply with these cGMP requirements and with FDA, state and foreign regulatory requirements or may terminate its agreement with us. Moreover, we have not entered into a commercial supply agreement with BI and BI has not demonstrated that it will be capable of manufacturing PRX302 on a large commercial scale.

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

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

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

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

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

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

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

- timing of market introduction of our products as well as competitive drugs;
- efficacy and safety of PRX302;
- the clinical indication(s) for which PRX302 is approved;
- continued projected growth of the urological disease markets, including incidence of BPH;
- acceptance by patients, primary care specialists and key specialists, including urologists;
- potential or perceived advantages or disadvantages of PRX302 over alternative treatments, including cost of treatment and relative convenience and ease of administration and length of sustained benefits from treatment;
- strength of sales, marketing and distribution support;
- the price of PRX302, both in absolute terms and relative to alternative treatments;
- the effect of current and future healthcare laws;
- availability of coverage and adequate coverage, reimbursement and pricing from government and other third-party payers; and
- product labeling or product insert requirements of the FDA or other regulatory authorities.

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

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

Market acceptance and sales of PRX302 will depend in large part on global reimbursement policies and may be affected by future healthcare reform measures, both in the United States and other key international markets. Successful commercialization of our product will depend in part on the availability of governmental and third-party payer reimbursement for the cost of PRX302 and/or payment to the physician for administering PRX302. Government health administration authorities, private health insurers and other organizations establish coverage and reimbursement policies for new products, including product candidates like PRX302. In particular, in the United States, private health insurers and other third-party payers often provide reimbursement for treatments based on the level at which the government (through the Medicare or

Medicaid programs) provides reimbursement for such treatments. In the United States, the EEA and other significant or potentially significant markets for our product candidate, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in Canada and the EEA will put additional pressure on product pricing, coverage, reimbursement and utilization, which may adversely affect our product sales and results of operations. These pressures can arise from policies and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, coverage and reimbursement policies and pricing in general.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. PPACA

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substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of PPACA of greatest importance to the pharmaceutical industry are the following: (i) an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs; (ii) an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively; (iii) a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D; (iv) extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (v) expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers Medicaid rebate liability; (vi) expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; (vii) expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance; and (viii) a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

We cannot predict whether legal challenges will result in changes to the PPACA or if other legislative changes will be adopted, or how such changes would affect our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers.

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

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

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

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

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The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

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

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

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

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

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

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, systems failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business

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

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

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

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

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

- decreased demand for our product or product candidates that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;

a diversion of management s time and our resources;

substantial monetary awards to clinical trial participants or patients;

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product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenue;

exhaustion of any available insurance and our capital resources;

the inability to commercialize our products or product candidates; and

a decline in our share price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies and commercial product sales in the amount of $10 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of any product, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and scientific and medical personnel, including our Executive Chairman, Lars Ekman, M.D., Ph.D., our Chief Executive Officer and President, Randall E. Woods, and our Chief Operating Officer and Head of Research and Development, Allison Hulme, Ph.D. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide incentive stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

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

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

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

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Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, or to report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

We are developing PRX302 for large patient populations served by urologists as well as general practice physicians, which number in the tens of thousands in the United States. Traditional pharmaceutical companies employ groups of sales representatives numbering in the thousands to call on this large of a number of physicians. We do not currently have an organization for the sale, marketing or distribution of PRX302 and we must build this organization or make arrangements with third parties to perform these functions in order to commercialize PRX302 and any future products. We intend to establish (either internally or through a contract sales force) a sales force to sell PRX302, if approved, in the United States. We plan to partner with third parties to commercialize PRX302 outside the United States.

The establishment and development of our own sales force or the establishment of a contract sales force to market any products we may develop in the United States will be expensive and time consuming and could delay any product launch, and we cannot be certain that we would be able to successfully develop this capacity. If we are unable to establish our sales and marketing capability or any other non-technical capabilities necessary to commercialize any products we may develop, we will need to contract with third parties to market and sell such products in the United States. We currently possess limited resources and may not be successful in establishing our own internal sales force or in establishing arrangements with third parties on acceptable terms, if at all.

Risks Related to Our Financial Position and Capital Requirements

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

Our operations have consumed substantial amounts of cash since inception. Since inception, we have raised approximately CND$54 million, or $54 million, as converted, from the sale of equity securities in private placements and public offerings as well as approximately CND$8 million, or $9 million, as converted, from the exercise of common share purchase warrants. In July 2011, we entered into the Oxford Loan for $15 million, which we are repaying over a 39-month period.

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

We expect that the net proceeds from this offering and our existing cash, together with interest thereon, will be sufficient to fund our operations through 2015, including through receipt of topline data from our first planned Phase 3 clinical trial. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. For example, our planned Phase 3 clinical trial may encounter technical, enrollment or other issues that could cause our development costs to increase more than we expected. In any event, we expect that we will require additional capital to complete development of PRX302, including completion of both of our planned Phase 3 clinical trials, and to obtain regulatory approval of and to commercialize PRX302.

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

- seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or

- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

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

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

We have a limited operating history and we have financed our operations primarily through equity and debt financings and have incurred significant operating losses since our inception. We had a net loss of $14.2 million and $21.2 million during the years ended December 31, 2011 and 2012, respectively, and $10.2 million and $2.8 million for the six months ended June 30, 2012 and 2013, respectively. As of June 30, 2013, we had an accumulated deficit of $76.5 million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders deficit and working capital. Our losses have resulted principally from costs incurred in our research activities for PRX302. We anticipate that our operating losses will substantially increase over the next several years as we continue development of PRX302, including the conduct of our planned Phase 3 clinical trials. In addition, if we obtain regulatory approval of PRX302, we may incur significant sales and marketing expenses and outsourced manufacturing expenses, as well as continued development expenses. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or whether or when we will become profitable.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements.

Our report from our independent registered public accounting firm for the year ended December 31, 2012 includes an explanatory paragraph stating that our losses and negative cash flows from operations and accumulated deficit at December 31, 2012 raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of

operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and it is likely that investors will lose all or a part of their investment. Future reports from our independent registered public accounting firm may also contain statements expressing doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

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

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

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

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

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

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

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

Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section entitled Use of Proceeds, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number

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and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management may not apply our cash from this offering in ways that ultimately increase the value of any investment in our securities. We expect to use our existing cash and net proceeds from this offering to fund the clinical development of PRX302, to make monthly principal and interest payments on our Oxford Loan through 2014 and for working capital, capital expenditures and general corporate purposes. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our shareholders. If we do not invest or apply our cash in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause the price of our common shares to decline.

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

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At June 30, 2013, we had $3.6 million of cash and cash equivalents. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents since June 30, 2013, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of cash equivalents owned by us.

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

We currently incur significant expenses denominated in foreign currencies, specifically in connection with our manufacturing and supply agreement with Boehringer Ingelheim RCV GmbH & Co KG for the manufacture of PRX302, for which payments are denominated in euro. In addition, we expect that we will utilize numerous clinical trial sites as part of our first Phase 3 clinical trial for PRX302 which will be located in various countries outside of the United States. We expect that these clinical trial sites will invoice us in the local currency of the site. We do not engage in foreign currency hedging arrangements for our accounts payable, and, consequently, foreign currency fluctuations may adversely affect our earnings. During the year ended December 31, 2012, 38.2% of our operating expenses were denominated in currencies other than the U.S. dollar. During the six months ended June 30, 2013, 28% of our operating expenses were denominated in currencies other than U.S. dollars. Going forward we anticipate that our sales and expenses, if any, will be denominated in the local currency of the country in which they occur. We may decide to manage this risk by hedging our foreign currency exposure, principally through derivative contracts. Even if we decide to enter into such hedging transactions, we cannot be sure that such hedges will be effective or that the costs of such hedges will not exceed their benefits. Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies, primarily the euro, could result in material amounts of cash being required to settle the hedge transactions or could adversely affect our financial results.

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Risks Related to our Intellectual Property

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

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

Composition-of-matter patents on the biological or chemical active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our patent applications covering composition-of-matter of PRX302 will be considered patentable by the U.S. Patent and Trademark Office, or U.S. PTO, and courts in the United States or by the patent offices and courts in foreign countries. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products off-label. Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to PRX302 fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them, and threaten our ability to commercialize, our products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals, the period of time during which we could market PRX302 under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to PRX302. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

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

The Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law in September 2011 and includes a number of significant changes to U.S. patent law. These include changes in the way patent applications will be prosecuted and may also affect patent litigation. The U.S. PTO is currently developing

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

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

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

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of PRX302. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. We are aware of at least one third-party patent that may be relevant to our product candidates. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further

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develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

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

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

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

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

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit

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formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

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

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

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

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

Risks Related to this Offering and Ownership of Our Common Shares

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

Generally, if for any taxable year 75% or more of our gross income is passive income, or at least 50% of the average quarterly value of our assets (which may be determined in part by the market value of our ordinary shares, which is subject to change) are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company, or PFIC, for United States federal income tax purposes. Based on the composition of our gross income and gross assets and the nature of our business, we expect that we were a PFIC for the taxable year ending December 31, 2012 and that we may be a PFIC for the taxable year ending December 31, 2013. In 2013 and for future years, our status as a passive foreign investment company will also depend on whether we are a controlled foreign corporation for U.S. federal income tax purposes, how

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quickly we utilize the cash proceeds from this offering in our business and other factors. If we are a PFIC for 2013 or any subsequent year, U.S. Holders (as defined in United States & Canadian Income Tax Considerations U.S. Federal Income Tax Information for U.S. Holders) of our shares may suffer adverse tax consequences. Gains realized by non-corporate U.S. Holders on the sale of our ordinary shares would be taxed as ordinary income, rather than as capital gain, and the preferential tax rate applicable to dividends received on our ordinary shares would be lost. Interest charges would also be added to taxes on gains and dividends realized by all U.S. Holders.

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

A U.S. Holder may also mitigate the adverse tax consequences of being a PFIC by timely making a mark-to-market election. Generally, for each year that we would meet the PFIC gross income or asset test, an electing U.S. Holder would include in gross income the increase in the value of its shares during each of its taxable years and deduct from gross income the decrease in the value of such shares during each of its taxable years. A mark-to-market election may be made and maintained only if our shares are regularly traded on a qualified exchange. While we anticipate that these requirements will be satisfied following this offering, whether our shares are regularly traded on a qualified exchange is an annual determination based on facts that, in part, are beyond our control. Accordingly, we can provide no assurances that a U.S. Holder will be eligible to make a mark-to-market election. See United States and Canadian Income Tax Considerations U.S. Federal Income Tax Information for U.S. Holders Passive Foreign Investment Company Consequences.

We do not know whether an active, liquid and orderly trading market in the United States will develop for our common shares or what the market price of our common shares will be and as a result it may be difficult for you to sell your common shares.

Prior to this offering, there has not been a U.S. public market for our common shares; however, our shares are listed and traded on the Toronto Stock Exchange, or the TSX. Although we have applied to list our common shares on the NASDAQ Global Market, an active trading market for our shares in the United States may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in our common shares is not active. The public offering price for the shares will be determined by negotiations between us and representatives of the underwriters and may not be indicative of prices that will prevail in the trading market. In addition, we will maintain our listing on the TSX, and maintaining a dual listing in both the United States and Canada may impact the market for our common shares on the TSX. Further, an inactive market in the United States may impair our ability to raise capital by selling our common shares and may impair our ability to enter into strategic partnerships or acquire companies or products by using our common shares as consideration.

Our common shares are listed for trade on more than one stock exchange, and this may result in price variations.

Our common shares currently trade on the TSX. Listing our common shares on the NASDAQ Global Market in addition to the TSX may increase share price volatility on the TSX and also result in volatility of the trading price on the NASDAQ Global Market because trading will be split between the two markets, resulting in less liquidity on both exchanges. In addition, different liquidity levels, volume of trading, currencies and market conditions on the two exchanges may result in different prevailing trading prices. As of August 1, 2013, the 52-week trading price of our common shares ranged from a low of CND$8.84, or $8.84, applying the conversion rate as of February 14, 2013, to a high of CND$20.28, or $20.28, applying the conversion rate as of August 22, 2012, after giving effect to the 52-for-1 share consolidation of our common shares. There is no guarantee that the market price of the common shares will not be subject to any such fluctuations in the future.

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The offering price for our common shares may bear no relationship to the price at which our common shares will trade upon the completion of this offering. The price at which our common shares will trade may be lower than the price at which they are sold in this offering. In addition, because the liquidity and trading patterns of securities listed on the TSX may be substantially different from those of securities quoted on the NASDAQ Global Market, historical trading prices may not be indicative of the prices at which our common shares will trade in the future on the NASDAQ Global Market. Further, there can be no assurance regarding the trading prices that will prevail on the TSX following our share consolidation of our common shares and our additional listing on the NASDAQ Global Market.

The financial reporting obligations of being a public company in the United States are expensive and time consuming, and may place significant additional demands on our management.

Prior to the consummation of this offering, we have not been subject to public company reporting obligations in the United States. The additional obligations of being a public company in the United States require significant additional expenditures and place additional demands on our management, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, and the listing requirements of the stock exchange on which our securities are listed. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, despite recent reforms made possible by the Jumpstart Our Business Startups Act, or the JOBS Act, the reporting requirements, rules, and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly, particularly after we are no longer an emerging growth company. Any changes that we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all.

We also expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These factors could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, particularly to serve on our audit and compensation committees, or as executive officers.

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

The trading price of our common shares is likely to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this Risk Factors section and elsewhere in this prospectus, these factors include:

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

inability to obtain adequate commercial supply for any approved product or inability to do so at acceptable prices;

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developments concerning our commercial partners, including but not limited to, those with manufacturers;

competition from existing technologies and products or new technologies and products that may emerge;

announcements of significant acquisitions, strategic partnerships, joint ventures, new products, capital commitments or other events by us or our competitors;

the inability to establish collaborations or termination of a collaboration;

actual or anticipated variations in our quarterly operating results;

failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;

our cash position;

announcement or expectation of additional financing efforts;

issuances of debt or equity securities;

our inability to successfully enter new markets or develop additional product candidates;

actual or anticipated fluctuations in our competitors operating results or changes in their growth rate;

sales of our common shares by us, or our shareholders in the future;

trading volume of our common shares on the NASDAQ Global Market and the trading volume and price of our common shares that are traded on the TSX;

market conditions in our industry;

overall performance of the equity markets and general political and economic conditions;

introduction of new products or services by us or our competitors;

additions or departures of key management, scientific or other personnel;

publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities or industry analysts;

changes in the market valuation of similar companies;

disputes or other developments related to intellectual property and other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies and product candidates;

changes in laws or regulations and policies applicable to product candidates, including but not limited to clinical trial requirements for approvals;

changes in accounting practices;

significant lawsuits, including patent or shareholder litigation; and

other events or factors, many of which are beyond our control.

Furthermore, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of our common shares. If the market price of our common shares after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

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

The trading market for our common shares in the United States will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If no securities or industry analysts commence coverage of our company, the trading price for our common shares in the United States may be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our common shares, changes their opinion of our shares or publishes inaccurate or unfavorable research about our business, our share price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common shares could decrease and we could lose visibility in the financial markets, which could cause our share price and trading volume to decline.

Our principal shareholders own a significant percentage of our shares and will be able to exert significant control over matters subject to shareholder approval.

As of July 10, 2013, entities affiliated with Tavistock Life Sciences Co., or Tavistock, owned approximately 30.5% of our outstanding voting shares and, upon completion of this offering, will hold approximately 11.5% of our outstanding voting shares (without giving effect to the potential purchase of any shares in this offering and assuming no exercise of the underwriters overallotment option).

Therefore, even after this offering Tavistock may have the ability to influence us through this ownership position. Tavistock may be able to determine all matters requiring shareholder approval. For example, it may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common shares that you may feel are in your best interest as one of our shareholders.

We will incur significant increased costs as a result of operating as a U.S. public company and maintaining a dual listing on the TSX and our management will be required to devote substantial time to new compliance initiatives.

As a U.S. listed public company, we will incur significant additional legal, accounting and other expenses that we did not incur as a company listed on the TSX, and accounting, reporting and other expenses in order to maintain a dual listing on both the NASDAQ Global Market and the TSX. These expenses will relate to, among other things, the obligation to present financial information according to International Financial Reporting Standards in Canada and according to U.S. GAAP in the United States. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the Securities and Exchange Commission, or SEC, and the NASDAQ Global Market have imposed various requirements on public companies. In July 2010, the Dodd-Frank Act was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say on pay and proxy access. Shareholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

Sales of a substantial number of our common shares in the public market by our existing shareholders, including our common shares currently listed on the TSX, could cause our share price to fall.

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

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We, along with our directors, executive management team, employees, Warburg Pincus Private Equity X, L.P. and its affiliates, and Tavistock, have agreed that for a period of 180 days after the date of this prospectus, subject to specified exceptions, we or they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any of our common shares. Subject to certain limitations, approximately 1,307,231 common shares will become eligible for sale upon expiration of such lock-up period, as calculated and described in more detail in the section entitled Shares Eligible for Future Sale. Shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will also be eligible for sale at that time. Sales of shares by these shareholders upon expiration of the lock-up period could have a material adverse effect on the trading price of our common shares. In addition, a significant number of our shares will not be subject to any lock-up arrangements in connection with this offering and will be freely tradable on the TSX, and any sales of these shares could also have a material adverse effect on the trading price of our common shares.

Certain holders of our common shares are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act, subject to the 180-day lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these shareholders could have a material adverse effect on the trading price of our common shares.

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

We expect that significant additional capital will be needed in the future to continue our planned operations, including commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To the extent we raise additional capital by issuing equity or convertible securities, our shareholders may experience substantial dilution. We may sell common shares, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common shares, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders.

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

If you purchase common shares sold in this offering, because the initial public offering price of our common shares will be substantially higher than the pro forma as adjusted net tangible book value per share following this offering, you will incur immediate and substantial dilution.

The initial public offering price will be substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding common shares immediately following this offering based on the total value of our tangible assets less our total liabilities. Therefore, if you purchase our common shares in this offering, you will incur immediate and substantial dilution in the amount of $1.91 per share, the difference between the initial public offering price per share of $5.00 and the pro forma as adjusted net tangible book value per share of our outstanding common shares as of June 30, 2013. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares. In addition, you may also experience additional dilution upon future equity and convertible debt issuances or the exercise of stock options to purchase common shares granted to our employees, consultants and directors under our stock option and equity incentive plans. As of June 30, 2013, options to purchase 300,590 common shares at a weighted average exercise

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price of CND$20.80 per share, or $19.78 per share as converted, and warrants exercisable for up to 918,868 common shares at an exercise price of CND$27.04 per share, or $25.71 per share as converted, were outstanding. See Dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation.

We are at risk of securities class action litigation.

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

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

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

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

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common shares held by non-affiliates exceeds $700 million as of any June 30 before that time or if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

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

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

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

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In addition, provisions in the BCBCA and in our articles, as amended and/or restated in connection with this offering, may have the effect of delaying or preventing changes in our management, including provisions that:

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

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

Risks Related To Being A Canadian Entity

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

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

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled Summary, 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 planned Phase 3 clinical trials of PRX302;
- our ability to obtain and maintain regulatory approval of PRX302, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations;
- our plans to research, develop and commercialize PRX302;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the market for PRX302, and our ability to serve that market;
- our ability to successfully commercialize PRX302, including our ability to develop sales and marketing capabilities, whether alone or with collaborators;
- the rate and degree of market acceptance of PRX302;
- our ability to obtain and maintain intellectual property protection for our current and any future product candidates and our ability to operate our business without infringing the intellectual property rights of others;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party clinical research organization manufacturer;
- the success of competing therapies that are or become available;
- the loss of key scientific or management personnel;

our expectations regarding the period during which we will be an emerging growth company under the JOBS Act;

our plans to evaluate development of PRX302 for prostate cancer;

our use of the proceeds from this offering; 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, intend, may, plan, predict, project, should, will, would, continue, ongoing or the negative of those terms or other 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

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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.

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USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $57.0 million (or approximately $66.0 million if the underwriters exercise their over-allotment option in full) from the sale of the common shares in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a U.S. public market for our common shares and to facilitate our future access to the U.S. public equity markets. We intend to use approximately $28.5 million of the net proceeds from this offering to fund the first planned Phase 3 clinical trial of PRX302 and approximately $10.5 million of the net proceeds from this offering to fund other ongoing clinical development of PRX302. We intend to use approximately $10.3 million of the net proceeds from this offering to make monthly principal and interest payments on our term loan with Oxford Finance LLC through 2014, in accordance with the terms of the Loan and Security Agreement dated July 15, 2011, as amended. The interest rate on the term loan, which is scheduled to mature on November 1, 2014, is 9.5%. We will use any remaining proceeds from this offering for general corporate purposes. We will have broad discretion in the use of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our stock. Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

We believe the net proceeds from this offering and our existing cash, together with interest thereon, will be sufficient to fund our operations through 2015, including through receipt of topline data from our first planned Phase 3 clinical trial.

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.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2013:

- on an actual basis derived from our unaudited consolidated financial statements and related notes appearing elsewhere in this prospectus; and
- on a pro forma as adjusted basis to additionally give effect to the sale by us of 13,000,000 common shares in this offering at the initial public offering price of $5.00 per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the related notes appearing elsewhere in this prospectus.

	As of June 30, 2013	
	Actual	Pro Forma As Adjusted
	(unaudited)	
	(in thousands, except per share amounts)	
Cash and cash equivalents	$ 3,570	$ 60,520
Promissory notes, including current portion	$ 9,351	$ 9,351
Shareholders equity:		
Common shares; no par value:		
an unlimited number of shares authorized, 3,149,869 shares issued and outstanding, actual;		
an unlimited number of shares authorized, shares issued and outstanding, pro forma as adjusted	54,215	111,165
Common share purchase warrants	6,045	6,045
Contributed surplus	8,904	8,904
Accumulated other comprehensive gain	253	253
Accumulated deficit	(76,456)	(76,456)
Total shareholders (deficit) equity	(7,039)	49,911
Total capitalization	$ 2,312	$ 59,262

The number of shares shown as issued and outstanding in the table above is based on the number of shares outstanding as of June 30, 2013 and excludes:

- 300,590 common shares issuable upon the exercise of options outstanding as of June 30, 2013 pursuant to our stock option plan, at a weighted-average exercise price of $19.78 per share;
- 14,376 common shares available for future issuance under our stock option plan as of June 30, 2013; and

918,868 common shares issuable upon the exercise of warrants outstanding as of June 30, 2013, at a weighted-average exercise price of $25.71 per share.

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DILUTION

If you invest in our common shares in this offering, your ownership interest may be diluted to the extent of the difference between the initial public offering price per share of our common shares and the pro forma as adjusted net tangible book value per share of our common shares immediately after this offering. The historical net tangible book value of our common shares as of June 30, 2013 was approximately $(7.0 million), or $(2.23) per share. Historical net tangible book value per share represents our total tangible assets (total assets less intangible assets) less our total liabilities, divided by the number of outstanding common shares.

Investors participating in this offering will incur immediate, substantial dilution. After giving effect to the receipt of the net proceeds from our sale of 13,000,000 common shares at the initial public offering price of $5.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2013 would have been approximately $49.9 million, or $3.09 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $5.32 per share to our existing shareholders and an immediate dilution of $1.91 per share to investors purchasing common shares in this offering.

The following table illustrates this dilution on a per share basis to new investors:

Initial public offering price per share		$ 5.00
Historical net tangible book value per share as of June 30, 2013	$ (2.23)	
Increase in net tangible book value per share attributable to new investors purchasing shares in this offering	5.32	
Pro forma as adjusted net tangible book value per share after giving effect to this offering		3.09
Dilution per share to new investors participating in this offering		$ 1.91

If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value per share would be $3.26 per share and the dilution per share to new investors in this offering would be $1.74 per share.

The table below summarizes as of June 30, 2013, on the pro forma as adjusted basis described above, the number of our common shares, the total consideration and the average price per share (i) paid to us by our existing shareholders after conversion to US$, using the conversion rate in effect on the date of this prospectus, and (ii) to be paid by new investors purchasing our common shares in this offering at the initial public offering price of $5.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
			(In thousands)		
Existing shareholders	3,149,869	20%	$ 62,888	49%	$ 19.97
New investors	13,000,000	80	65,000	51	5.00
Total	16,149,869	100.0%	$ 127,888	100.0%	

Certain of our existing shareholders and their affiliated entities, including entities affiliated with Tavistock, have agreed to purchase approximately $22.4 million of our common shares in this offering at the public offering price.

Except as otherwise indicated, the discussion and tables above assume no exercise of the underwriters over-allotment option or any outstanding options or warrants. If the underwriters exercise their over-allotment option

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in full, the number of common shares held by existing shareholders will be reduced to 17% of the total number of common shares to be outstanding after this offering, and the number of common shares held by investors participating in this offering will be further increased to 14,950,000, or 83% of the total number of common shares to be outstanding after this offering.

The above discussion and tables are based on 3,149,869 common shares outstanding as of June 30, 2013 and the 13,000,000 common shares included in this offering, and exclude:

- 300,590 common shares issuable upon the exercise of outstanding options as of June 30, 2013 pursuant to our stock option plan, at a weighted-average exercise price of $19.78 per share;
- 14,376 common shares available for future issuance under our stock option plan as of June 30, 2013; and
- 918,868 common shares issuable upon the exercise of warrants outstanding as of June 30, 2013 at a weighted-average exercise price of $25.71 per share.

To the extent that any outstanding options or warrants are exercised, new options are issued under our stock option plan or we issue additional common shares in the future, there will be further dilution to investors participating in this offering. If all outstanding options under our stock option plan and warrants outstanding as of June 30, 2013 were exercised, then our existing shareholders, including the holders of these options and warrants, would own 25%, and our new investors would own 75%, of the total number of our common shares outstanding upon the closing of this offering. In such event, the total consideration paid by our existing shareholders, including the holders of these options and warrants, would be approximately $92.5 million, or 59% of the total consideration paid to us by our shareholders, the total consideration paid by our new investors would be $65.0 million, or 41% of the total consideration paid to us by our shareholders, the average price per share paid by our existing shareholders would be $21.16 and the average price per share paid by our new investors would be $5.00.

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SELECTED CONSOLIDATED FINANCIAL DATA

The following table sets forth our selected consolidated financial data. We derived the selected consolidated statement of operations data for the years ended December 31, 2011 and 2012 from our audited consolidated financial statements and related notes appearing elsewhere in this prospectus. We derived the selected consolidated statement of operations data for the six months ended June 30, 2012 and 2013 and the consolidated balance sheet data as of June 30, 2013 from our unaudited consolidated interim financial statements and related notes appearing elsewhere in this prospectus. The unaudited consolidated interim financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to fairly state our financial position as of June 30, 2013 and results of operations for the six months ended June 30, 2012 and 2013. Our historical results are not necessarily indicative of the results that may be achieved in the future and results of interim periods are not necessarily indicative of the results for the entire year. The selected consolidated financial data should be read together with our consolidated financial statements and related notes, and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus. Our audited consolidated annual financial statements and unaudited consolidated interim financial statements have been prepared in U.S. dollars in accordance with U.S. GAAP.

	Years Ended December 31,		Six months ended June 30,	
	2011	2012	2012	2013
			(unaudited)	
	(in thousands, except per share data)			
Consolidated Statement of Operations Data:				
Revenues	$	$	$	$ 5,000
Operating expenses:				
Research and development	8,660	13,523	6,783	4,025
General and administrative	4,635	5,685	2,362	2,126
Total operating expenses	13,295	19,208	9,145	6,151
Other income (expense)				
Interest income (expense) net	(895)	(1,880)	(1,004)	(751)
Other income (expense) net	(11)	(106)	(84)	(356)
Total other income (expense)	(906)	(1,986)	(1,088)	(1,107)
Net loss before income tax expense	(14,201)	(21,194)	(10,233)	(2,258)
Income tax expense				(500)
Net loss	$ (14,201)	$ (21,194)	$ (10,233)	$ (2,758)
Basic and diluted net loss per common share[1][2]	$ (6.05)	$ (6.94)	$ (3.46)	$ (0.88)
Shares used to calculate net loss per common share[1][2]	2,345	3,054	2,956	3,150

(1) See Note 3 of our Notes to the Consolidated Financial Statements for an explanation of the method used to calculate the basic and diluted net loss per common share and the number of shares used in the computation of the per share amounts.
(2) Reflects the 52-for-1 share consolidation of our common shares.

	As of December 31,		As of June 30,
	2011	2012	2013
	(in thousands)		(unaudited)
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 23,410	$ 9,721	$ 3,570

Working capital (deficit)	17,944	814	(3,991)
Total assets	24,800	11,529	6,348
Promissory notes, including current portion	14,702	12,021	9,351
Accumulated deficit	(52,504)	(73,698)	(76,456)
Total shareholders equity (deficit)	6,997	(5,105)	(7,039)

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MANAGEMENT S DISCUSSION AND ANALYSIS

OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Our functional currency is Canadian dollars and our reporting currency is U.S. dollars. All dollar amounts are expressed in U.S. dollars unless otherwise noted. All amounts expressed on an as-converted basis are calculated using conversion rates as of June 30, 2013 unless otherwise noted.

On August 9, 2013, our board of directors approved a 52-for-1 share consolidation of our issued and outstanding common shares, subject to approval by the Toronto Stock Exchange. The accompanying disclosures give retroactive effect to the share consolidation for all periods presented. The Company s stock option plan and outstanding warrants provide for a pro-rata adjustment to the number of shares issuable upon the exercise of outstanding stock options and warrants in the event of a share consolidation. The effects of the share consolidation have been given retroactive effect to the related disclosures of outstanding stock options and warrants.

Overview

Background

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 Toronto Stock Exchange. We are currently developing PRX302 as a treatment for the symptoms of benign prostatic hyperplasia, or BPH, commonly referred to as an enlarged prostate. PRX302 is designed to be a convenient treatment that is safer and less invasive than surgery and more effective and better tolerated than currently approved pharmaceutical therapies. In our Phase 2b clinical trial, we saw significant symptom relief from a single treatment of PRX302 that was sustained throughout the follow-up period of 12 months, and there were no drug-related erectile dysfunction or cardiovascular side effects reported. In 2009, we licensed exclusive rights to PRX302 from UVIC Industry Partnerships Inc., or UVIC, and The Johns Hopkins University, or Johns Hopkins, for the treatment of the symptoms of BPH. In April 2010, we entered into an exclusive license agreement with Kissei Pharmaceuticals Co., Ltd., or Kissei, pursuant to which we granted Kissei the right to develop and commercialize PRX302 in Japan for the treatment of the symptoms of BPH, prostate cancer, prostatitis or other diseases of the prostate.

We expect to initiate the first of two planned Phase 3 clinical trials of PRX302 for the treatment of the symptoms of BPH in the second half of 2013. We intend to enroll approximately 440 patients in the first planned Phase 3 clinical trial.

On April 18, 2011, we announced the relocation of our core activities from Vancouver, British Columbia to San Diego, California.

Kissei Pharmaceuticals License Agreement

In April 2010, we received an up-front payment of $3.0 million from Kissei under our license agreement. During the six months ended June 30, 2013, we recorded as revenue a $5.0 million non-refundable milestone

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payment due from Kissei upon the achievement of certain development activities, as such milestone had been achieved during this period. We received payment for the milestone in April 2013. We are eligible to receive additional milestone payments of up to $67.0 million upon our achievement of specified development, regulatory and commercial milestones 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. Kissei is not currently studying PRX302 for the treatment of BPH, prostate cancer, prostatitis or other diseases of the prostate.

Warburg Pincus Financing

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., together 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 of the initial tranche of CND$10 million, or $9.8 million, as converted, applying the conversion rate as of the date of closing November 2010, the 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 the third tranche of CND$8.3 million, or $8.3 million, as converted, applying the conversion rate as of the date of closing March 2012. In accordance with the terms of the Investment Agreement, Warburg Pincus ability to make additional investments under the Investment Agreement expired on September 30, 2012 with Warburg Pincus making a total investment of CND$26.6 million, or $26.3 million, as converted, as of such time. As of July 10, 2013, Warburg Pincus held 0.8 million common share purchase warrants with an exercise price of CND$26.00 per common share, or $24.96 per common share as converted. The Investment Agreement was terminated in July 2013. The termination of the Investment Agreement had no effect on the outstanding common share purchase warrants held by Warburg Pincus.

Oxford Financing

In July 2011, we entered into a $15 million Loan and Security Agreement with Oxford Finance LLC, or Oxford, which we amended in January 2013 and again in July 2013, and which we refer to as the Oxford Loan. Under the terms of the Oxford Loan, we made interest-only payments for nine months at a fixed rate of 9.5%. Subsequent to the interest-only payments, the note is amortized with principal and interest payments due through the remaining term of the loan. Pursuant to the July 2013 amendment, Oxford authorized us to make an interest only payment on August 1, 2013. We will resume making principal and interest payments on September 1, 2013 in accordance with the terms of the second amendment. The loan term, including interest only period, is 39 months with a maturity date of November 1, 2014; however, the loan can be prepaid subject to certain provisions and prepayment fees. Upon final repayment of the Oxford Loan on the maturity date, by prepayment, or upon acceleration of the Oxford Loan, we also

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must make an additional final payment of $0.8 million, which is being accreted as additional interest expense over the term of the loan. If the loan is prepaid or accelerated, the following amounts are due: all outstanding principal plus all accrued and unpaid interest, the final payment of $0.8 million, a prepayment fee and any other sums due under the Oxford Loan, including certain of Oxford s expenses, as well as interest at the default rate for any past due amounts. The prepayment fee is set at two percent of the outstanding principal being prepaid if the loan is prepaid prior to July 2013 and one percent of the outstanding principal being prepaid if the loan is prepaid after July 2013. To secure our repayment obligations under the Oxford Loan, Oxford obtained a first priority security interest in all of our assets, including intellectual property and all of our equity interests in Sophiris Bio Corp and Sophiris Bio Holding Corp. The loan is subject to customary covenants and events of default, including, among others, restrictions on transferring or licensing our assets, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on our assets, in each case subject to customary exceptions. If we default under our Oxford Loan, Oxford may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations.

In connection with the Oxford Loan, we entered into an investment letter agreement, or the Investment Letter, with Oxford, which grants Oxford the right to purchase up to $1 million of specified securities in connection with a qualified financing involving the private sale of our common shares or common-convertible securities through October 2014, subject to additional restrictions described in the Investment Letter.

PRX302 License Agreement for BPH

In 2009, we licensed exclusive rights to PRX302 under an agreement with UVIC and Johns Hopkins with respect to the use of PRX302 for the treatment of the symptoms of BPH and other non-cancer diseases and conditions of the prostate, with the exception of prostate cancer. The license agreement requires us to make payments of CND$1.3 million, or $1.2 million, as converted, on the achievement of certain clinical and regulatory milestones and to pay royalties on commercial sales of resulting products. During the six months ended June 30, 2013, we expensed a $0.1 million milestone payment due under the license agreement upon the completion of our last Phase 2b clinical trial prior to commencing a Phase 3 clinical trial. We anticipate paying this milestone upon the enrollment of our first patient in a Phase 3 clinical trial for the treatment of the symptoms of BPH. We anticipate initiating our Phase 3 clinical trial in the second half of 2013. This amount was expensed to research and development expense. In addition, in the second quarter of 2013 we paid UVIC and Johns Hopkins a sub-license royalty of $0.4 million payable under the license agreement associated with our $5.0 million milestone payment from Kissei. This amount was recorded as a component of research and development expense.

From the inception of the agreement, we have incurred sub-license fees of $0.6 million and milestone payments of $0.1 million under this agreement.

PRX302 License Agreement for Prostate Cancer

In 2004, we licensed exclusive rights to PRX302 for the treatment of prostate cancer under an agreement with UVIC and Johns Hopkins. We have agreed to make cumulative milestone payments over the lifecycle of PRX302 of up to CND$3.6 million, or $3.4 million, as converted, contingent upon the achievement of certain clinical and regulatory milestones and to pay royalties on commercial sales of resulting products. Through June 30, 2013, we have paid milestone payments of CND$0.1 million, or $0.1 million, applying the conversion rate for the year of the payment. We have to date completed two clinical trials in patients with prostate cancer, and we will continue to evaluate future development in this indication.

Financial Operations Overview

Revenues

Our revenues to date consist of a $3.0 million up-front payment received from Kissei in 2010 and a $5.0 million non-refundable milestone payment for our achievement of certain development activities during the

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six months ended June 30, 2013. We have no products approved for sale, and we have not generated any revenues from product sales.

Other than potential development milestones from Kissei, we do not expect to receive any revenues from PRX302 until we obtain regulatory approval and commercialize such product or until we potentially enter into additional collaborative agreements with third parties for the development and commercialization of PRX302, which additional agreements will not likely occur until we complete the development of PRX302. If our development efforts for PRX302, or the efforts or Kissei or any future collaborator, results in clinical success and regulatory approval or collaboration agreements with other third parties, we may generate revenues from PRX302. However, we may never generate revenues from PRX302 as we or any collaborator may never succeed in obtaining regulatory approval or commercializing this product.

Research and Development Expenses

Research and development expenses can be driven by a number of factors including: (a) the scope of clinical development and research programs pursued; (b) the type and size of clinical trials undertaken; (c) the number of clinical trials that are active during a particular period of time; (d) the rate of patient enrollment; (e) regulatory activities to support the clinical programs; and (f) Chemistry, Manufacturing and Controls, or CMC, activities associated with process development, scale-up and manufacture of drugs used in clinical trials; and such expenses are ultimately a function of decisions made to continue the development and testing of a product candidate based on supporting safety and efficacy results from clinical trial.

The majority of our operating expenses to date have been incurred in research and development activities related to PRX302. Research and development expenses include:

- external research and development expenses incurred under agreements with clinical research organizations, or CROs, and investigative sites and clinical trial costs, as well as payments to consultants;
- employee related expenses, including salaries, benefits, travel and stock-based compensation expense;
- third-party manufacturing expenses; and
- facilities, depreciation and other allocated expenses.

We expense research and development costs as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been consumed. Since our inception in January 2002, we have incurred a total of $53.7 million in research and development expenses through June 30, 2013.

At this time, due to the risks inherent in the clinical trial process and given the early stage of our product development program, we are unable to estimate with any certainty the costs we will incur in the continued development of PRX302 for potential approval and commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. However, we do expect our research and development expenses to increase for the foreseeable future as we advance PRX302 into our first Phase 3 clinical trial, which we plan to initiate in the second half of 2013. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals, could lead to increased research and development expense and, in turn, have a material adverse effect on our results of operations.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, business development, market research and support functions.

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Other general and administrative expenses include allocated facility-related costs not otherwise included in research and development expenses, travel expenses, market research expenses and professional fees for auditing, tax and legal services. We expect that general and administrative expenses will increase in the future as we expand our operating activities and incur additional costs associated with being a dual-listed U.S. and Canadian publicly traded company. These increases will likely include professional fees and directors and officers liability insurance premiums.

Interest Income (Expense), Net

We earn interest income from interest-bearing cash accounts. Interest expense primarily represents interest payable to Oxford, accretion of our debt discount and amortization of our issuance costs associated with our Oxford Loan.

Other Income (Expense), Net

Other income (expense), net consists primarily of foreign exchange gains and losses and on occasion income or expense of a non-recurring nature. Foreign exchange gains and losses result from the settlement of foreign currency transactions and from the remeasurement of monetary assets and liabilities denominated in currencies other than our functional currency.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in conformity with generally accepted accounting principles in the United States. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the revenues and expenses incurred during the reported periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in the notes to our consolidated financial statements appearing at the end of this prospectus, we believe that the following accounting policies are critical to understanding and evaluating our reported financial results.

Foreign Currency

Functional Currency

Historically the functional currency of Sophiris Bio Inc. has been the Canadian dollar and the functional currency of each of our subsidiaries, Sophiris Bio Corp. and Sophiris Bio Holding Corp., has been the U.S. dollar. As a result of being a U.S. publicly traded company, the functional currency of Sophiris Bio Inc. could be transitioned from the Canadian dollar to the U.S. dollar if the underlying indicators point to a transition in the currency of the primary economic environment in which Sophiris Bio Inc. operates.

Historically, we have issued the common share purchase warrants of Sophiris Bio Inc. with exercise prices denominated in Canadian dollars. Upon the issuance of common share purchase warrants we calculate the fair value of the issued common share purchase warrants utilizing the Black-Scholes valuation model. The calculated fair value is then recorded as a component of common share purchase warrants on the balance sheet. The fair value is not remeasured in future periods.

If this change in functional currency occurs, it would impact how Sophiris Bio Inc. accounts for our warrants which have exercise prices denominated in Canadian dollars. Upon a change in our functional currency,

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we anticipate recording a liability equal to the fair market value of the warrants in accordance with Accounting Standards Codification, or ASC, 815, *Derivatives and Hedging* and the initial fair value recorded as a component of common share purchase warrants will be reversed. At each future reporting period, we will adjust the fair value of the warrant liability and any corresponding increase or decrease to the warrant liability will be recorded as a component of other income (expense) on the statement of operations and comprehensive loss. We will calculate the warrant liability utilizing a Black-Scholes valuation model.

Reporting Currency

For presentation purposes, our assets and liabilities are translated to U.S. dollars at exchange rates at the reporting date. The income and expenses are translated to U.S. dollars at the average exchange rate for the period in which the transaction arose. Equity transactions are translated at the spot exchange rates on which the transactions occur. Exchange differences arising are recognized in a separate component of equity titled accumulated other comprehensive loss. The consolidated financial statements have been presented in a currency other than Sophiris Bio Inc. s functional currency of the Canadian dollar as management has determined that the U.S. dollar is the common currency in which our peers, being international drug and pharmaceutical companies, present their financial statements.

Transactions and Balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of foreign currency transactions and from the remeasurement of monetary assets and liabilities denominated in currencies other than our functional currency are recognized in the other income (expense).

Revenue Recognition

We may enter into product development agreements which may include nonrefundable signing and licensing fees, milestone payments and royalties on any product sales derived from collaborations. These multiple element arrangements are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. License fees are recognized as revenue when persuasive evidence of an arrangement exists, the fee is fixed or determinable, delivery or performance has substantially completed and collection is reasonably assured.

We recognize up front license payments as revenue upon delivery of the license only if the license has stand-alone value to the customer and if the agreement includes a general right of return, the delivery or performance of undelivered items is considered probable and within our control. The payment is generally allocated to the separate units of accounting based on their relative selling prices. The selling price of each deliverable is determined using vendor specific objective evidence of selling prices, if it exists; otherwise, third-party evidence of selling prices. If neither vendor specific objective evidence or third-party evidence exists, we use our best estimate of the selling price for each deliverable. The payment allocated is limited to the amount that is not contingent on the delivery of additional items or fulfillment of other performance conditions.

Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which the performance obligations will be performed and revenue will be recognized. If we cannot reasonably estimate the timing and the level of effort to complete our performance obligations under the arrangement, then revenue under the arrangement is recognized on a straight-line basis over the period we are expected to complete our performance obligations.

We evaluate milestone payments on an individual basis and recognize revenue from non-refundable milestone payments when the earnings process is complete and the payment is reasonably assured. We recognize non-refundable milestone payments related to arrangements under which we have continuing performance obligations as

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revenue upon achievement of the associated milestone, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with the milestone event. We record any amounts we receive under agreements in advance of performance, if deemed substantive, as deferred revenue and recognize such amount as revenue as we complete our performance obligations. A milestone event is considered substantive if (i) the milestone is commensurate with either (a) our performance to achieve the milestone or (b) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) it relates solely to past performance and (iii) it is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. If any portion of the milestone payment does not relate to our performance, does not relate solely to past performance or is refundable or adjustable based on future performance, the milestone is not considered to be substantive. Milestone payments are not bifurcated into substantive and non-substantive components. Payments related to the achievement of non-substantive milestones are deferred and recognized over the Company s remaining performance period.

Royalty revenue will be recognized upon the sale of the related products provided we have no remaining performance obligations under the arrangement.

Accrued Research and Development Expenses

Clinical trial costs are recorded as a component of research and development expenses. We accrue and expense clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with CROs and clinical trial sites. We determine the estimates through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including our clinical development plan. The process of estimating clinical trial costs may become more complex as our planned Phase 3 clinical trials will involve larger numbers of patients and clinical sites.

Substantially all of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Adjustments to prior period estimates have not been material for each of the years ended December 31, 2011 and 2012. Based on the amount of accrued research and development expenses as of December 31, 2012, it is our assessment that deviations between our estimated and actual amounts of 5% or less would not have a material impact on our research and development expenses.

Examples of estimated accrued research and development expenses include:

- fees paid to CROs in connection with clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to vendors in connection with preclinical development activities;
- fees paid to vendors associated with the development of companion diagnostics; and
- fees paid to vendors related to product manufacturing, development and distribution of clinical supplies.

Nonrefundable advance payments for goods and services that will be used or rendered in future research and development activities are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

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Primarily all of our research and development expenses related to PRX302 during the years ended December 31, 2011 and 2012 and the six months ended June 30, 2012 and 2013. We recognized research and development expenses as follows (in thousands):

	Years ended December 31,		Six months ended June 30,	
	2011	2012	2012	2013
			(unaudited)	
Clinical research and development	$ 4,691	$ 7,075	$ 2,991	$ 2,993
Non-clinical research and development	346	1,149	965	3
Manufacturing	3,306	5,151	2,736	905
Stock-based compensation expense	317	148	91	124
	$ 8,660	$ 13,523	$ 6,783	$ 4,025

Stock-based Compensation

We expense the fair value of employee stock options over the vesting period. Stock-based compensation expense is measured using the fair value of the award at the grant date, net of estimated forfeitures, and is adjusted annually to reflect actual forfeitures. The fair value of each stock-based award is estimated using the Black-Scholes valuation model and is expensed using graded amortization over the vesting period.

We recognized stock-based compensation expense as follows (in thousands):

	Years ended December 31,		Six months ended June 30,	
	2011	2012	2012	2013
			(unaudited)	
Research and development	$ 317	$ 148	$ 91	$ 124
General and administrative	598	528	253	401
Total	$ 915	$ 676	$ 344	$ 525

The fair value of options granted for the years ended December 31, 2011 and 2012 and the six months ended June 30, 2013 were estimated at the date of grant using the following assumptions:

	Years ended December 31,		Six months ended June 30,	
	2011	2012	2012	2013
			(unaudited)	
Expected life of the option term (years)	4.5	3.9	4.0	4.2
Risk-free interest rate	1.93%	1.24%	1.44%	1.38%
Dividend yield	0%	0%	0%	0%
Volatility	74.8%	73.9%	75.5%	69.1%
Forfeiture rate	8.7%	9.0%	7.8%	8.8%
Estimated weighted-average fair value per stock option (CND$)	$ 16.12	$ 8.84	$ 13.52	$ 7.80

Expected Life of the Option Term This is the period of time that the options granted are expected to remain unexercised. Options granted during the year have a maximum contractual term of five years. We estimate the expected life of the option term based on actual past behavior for similar options.

Risk-Free Interest Rate This is the Canadian Treasury rate for the week of each option grant during the quarter having a term that most closely resembles the expected life of the option.

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Dividend Yield We have never declared or paid dividends on common shares and have no plans to do so in the foreseeable future.

Volatility Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated or is expected to fluctuate during a period. We considered the historical volatility from our Canadian initial public offering through the dates of grants.

Forfeiture Rate Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We assess the forfeiture rate on an annual basis and revises the rate when deemed necessary.

Net Operating Loss Carryforwards

As of December 31, 2012, we had Canadian and U.S. federal tax net operating loss carryforwards of $62.4 million and $39 thousand, respectively, which begin to expire in 2013 and 2031, respectively. As of December 31, 2012, we also had Canadian and U.S. federal investment tax credits of $3.0 million and $68 thousand, respectively. The Canadian and U.S. federal investment tax credits will begin to expire in 2015 and 2031, respectively.

Utilization of the U.S. federal net operating losses and credits may be subject to a substantial annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986, as amended. The annual limitation may result in the expiration of our net operating losses and credits before we can use them. We have recorded a valuation allowance for the full amount of the deferred tax asset related to our net operating loss and research and development tax credit carryforwards.

Jobs Act

In April 2012, the JumpStart Our Business Startups Act of 2012, or the JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, we are electing not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable. In addition, we are in the process of evaluating the benefits of relying on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an emerging growth company we choose to rely on such exemptions, we may not be required to, among other things, (i) provide an auditor s attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer s compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of our initial public offering or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

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Results Of Operations

Comparison of the Six Months Ended June 30, 2012 and 2013

The following table summarizes the results of our operations for the six months ended June 30, 2012 and 2013, together with the changes in those items in dollars (in thousands):

	Six months ended June 30, 2012	2013	Change 2012 vs. 2013
License revenue	$	$ 5,000	$ 5,000
Research and development expenses	6,783	4,025	(2,758)
General and administrative expenses	2,362	2,126	(236)
Interest income (expense), net	(1,004)	(751)	253
Other income (expense), net	(84)	(356)	(272)
Income tax expense		(500)	(500)

License revenue. During the six months ended June 30, 2013, we recorded as revenue a $5.0 million non-refundable milestone payment due from Kissei upon our achievement of certain development activities, as such milestone had been achieved during this period.

Research and development expenses. Research and development expenses were $4.0 million for the six months ended June 30, 2013 and $6.8 million for the six months ended June 30, 2012, a decrease of $2.8 million. The decrease in research and development costs is primarily attributable to a $1.0 million decrease in the costs associated with our non-clinical activities, specifically a repeat dose monkey study and a rat fertility study both of which were completed in 2012. In addition, the costs associated with the transfer and scale-up of manufacturing activities for PRX302 decreased approximately $1.8 million from the six months ended June 30, 2012 to the six months ended June 30, 2013. Offsetting this decrease is a $0.4 million sub-license royalty fee which was expensed during the six months ended June 30, 2013 due to UVIC Industry Partnerships and The Johns Hopkins University associated with our $5.0 million milestone payment from Kissei. The research and development costs included stock-based compensation charges of $0.1 million for both the six months ended June 30, 2013 and the six months ended June 30, 2012.

General and administrative expenses. General and administrative expenses were $2.1 million for the six months ended June 30, 2013 compared to $2.4 million for the six months ended June 30, 2012. The decrease of $0.2 million is due to a reduction in personnel related costs and marketing research costs, offset partially by an increase in accounting and tax professional fees and stock compensation expense. The general and administrative cost included stock based compensation expense of $0.4 million for the six months ended June 30, 2013 as compared to $0.3 million for the six months ended June 30, 2012, an increase of $0.1 million.

Interest income (expense), net. Interest expense, net was $0.8 million for the six months ended June 30, 2013 and $1.0 million in the same period in 2012, a decrease of $0.3 million. This decrease resulted from a decrease in interest expense related to the Oxford Loan of approximately $0.3 million during the six months ended June 30, 2013 compared to the six months ended June 30, 2012. The interest expense related to the Oxford Loan is expected to decline over the term of the loan as the total principal outstanding on the loan is paid down.

Other income (expense), net. Other income (expense), net was ($0.4 million) for the six months ended June 30, 2013 as compared to ($0.1 million) for the six months ended June 30, 2012, a change of ($0.3 million.) This change was primarily due to a $0.3 million increase in foreign exchange loss from the six months ended June 30, 2012 to the same period in 2013. These foreign exchange losses resulted from the settlement of foreign currency transactions.

Income tax expense. The $5.0 million milestone payment from Kissei was subject to a 10% Japanese withholding tax. As a result, we recorded income tax expense of $0.5 million for the six months ended June 30, 2013. We will be eligible to utilize the withholding tax to offset future taxes due in Japan.

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Given the uncertainty around our ability to generate future taxable income, we have expensed the withholding tax during the six months ended June 30, 2013.

Comparison of the Years Ended December 31, 2011 and 2012

The following table summarizes the results of our operations for the years ended December 31, 2011 and 2012, together with the changes in those items in dollars (in thousands):

	Years ended December 31,		
	2011	2012	Change 2011 vs. 2012
Research and development expenses	$ 8,660	$ 13,523	$ 4,863
General and administrative expenses	4,635	5,685	1,050
Interest income (expense), net	(895)	(1,880)	(985)
Other income (expense), net	(11)	(106)	(95)

Research and development expenses. Research and development expenses were $13.5 million in the year ended December 31, 2012 and $8.7 million in the year ended December 31, 2011, an increase of $4.8 million. This increase was primarily attributable to an increase of $0.4 million associated with our ongoing Phase 1/2 transrectal clinical trial, which began enrollment in September 2011, an increase of $2.0 million of costs associated with our first planned Phase 3 clinical trial and an increase of $1.8 million in our costs associated with the transfer and scale-up of manufacturing activities for PRX302 clinical trial material. Also included as a component of research and development expense during the year ended December 31, 2011 is $0.4 million for severance related costs associated with the shut-down of our Vancouver operations. The research and development expense included stock-based compensation charges of $0.1 million for the year ended December 31, 2012 as compared to $0.3 million for the year ended December 31, 2011. The decrease in the stock-based compensation charges is related to the acceleration of stock options for our former senior management team during 2011.

General and administrative expenses. General and administrative expenses were $5.7 million in the year ended December 31, 2012 and $4.6 million for the year ended December 31, 2011, an increase of $1.1 million. Included in our general and administrative expenses for the year ended December 31, 2011 was $0.7 million of severance related costs associated with the shut-down of our Vancouver operations. Excluding the severance related costs of $0.7 million from our year ended December 31, 2011 operating results, our general and administrative expenses increased $1.8 million for the year ended December 31, 2012 as compared to the year ended December 31, 2011. This increase primarily relates to an increase in personnel related costs associated with the build-out of our San Diego general and administrative group of approximately $0.6 million, an increase in professional fees of approximately $0.5 million and an increase in market research costs of approximately $0.6 million. Included in general and administrative expense are stock-based compensation charges of $0.5 million for the year ended December 31, 2012 compared to $0.6 million for the year ended December 31, 2011.

Interest income (expense), net. Interest expense, net was $1.9 million in the year ended December 31, 2012 and $0.9 million in the same period in 2011, an increase of $1.0 million. This increase resulted from an increase in interest expense related to the Oxford Loan of approximately $1.0 million during the year ended December 31, 2012 compared to the year ended December 31, 2011. The Oxford Loan originated during July 2011. As such, there is an increase in interest expense related to this loan during the year ended December 31, 2012 compared to the year ended December 31, 2011.

Other income (expense), net. Other income (expense), net was ($0.1 million) for the year ended December 31, 2012 as compared to $11 thousand for the year ended December 31, 2011, a change of ($0.1 million.) This change was primarily due to a $0.1 million increase from 2011 to 2012 in foreign exchange loss. These foreign exchange losses resulted from the settlement of foreign currency transactions.

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Liquidity and Capital Resources

Since our inception, our operations have been primarily financed through public and private sales of our common shares and a debt financing. Since inception, we have devoted our resources to funding research and development programs, including discovery research, preclinical studies and clinical trial activities.

At June 30, 2013, we had cash and cash equivalents of $3.6 million, representing a net decrease of $6.2 million from December 31, 2012. We had a working capital deficit of $(4.0) million at June 30, 2013, a decrease of $4.8 million from December 31, 2012. The decrease in our working capital from December 31, 2012 to June 30, 2013 was the result of our utilization of cash to fund operations during the six months ended June 30, 2013. At June 30, 2013, we had an accumulated deficit of $76.5 million.

The following table shows a summary of our cash flows for the years ended December 31, 2011 and 2012 and the six months ended June 30, 2012 and 2013 (in thousands):

	Years ended December 31,		Six months ended June 30,	
	2011	2012	2012	2013
			(unaudited)	
Net cash provided by (used in):				
Operating activities	$ (12,342)	$ (19,047)	$ (8,936)	$ (2,140)
Investing activities	(254)	(26)	(21)	(3)
Financing activities	23,517	5,095	7,840	(3,918)
Effect of exchange rate changes on cash and cash equivalents	108	289	(141)	(90)
Net increase (decrease) in cash and cash equivalents	$ 11,029	$ (13,689)	$ (1,257)	$ (6,151)

Operating Activities

Net cash used in operating activities was $12.3 million and $19.0 million for the years ended December 31, 2011 and 2012, respectively, and $8.9 million and $2.1 million for the six months ended June 30, 2012 and 2013, respectively. The increase in net cash used between the years ended December 31, 2011 and 2012 was primarily due to the increase in operating losses due to increases in cash payments associated with research and development activities in 2012 when compared to the same period in 2011. The decrease in net cash used between the six months ended June 30, 2012 to the six months ended June 30, 2013 was primarily related to the receipt of a $5.0 million milestone payment from Kissei during the six months ended June 30, 2013.

Investing Activities

Net cash used in investing activities during the years ended December 31, 2011 and 2012 and the six months ended June 30, 2012 and 2013 primarily related to the purchase of property and equipment used for general operating purposes.

Financing Activities

Net cash provided by (used in) financing activities was $23.5 million and $5.1 million for the years ended December 31, 2011 and 2012, respectively, and $7.8 million and $(3.9) million for the six months ended June 30, 2012 and 2013, respectively. In 2011, $15.0 million was received from the issuance of promissory notes, $8.1 million, net of issuance costs was received from the issuance of common shares from the private placement of stock and $0.4 million was received from the exercise of stock options and warrants.

Net cash provided by financing activities during the year ended December 31, 2012 was primarily related to the issuance of common shares from a private placement which resulted in net proceeds of $8.3 million. The receipt of cash from the private placement was offset by principal payments to Oxford of $3.2 million during the year ended December 31, 2012.

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Net cash provided by financing activities during the six months ended June 30, 2012 was primarily related to the issuance of common shares from a private placement which resulted in net proceeds of $8.3 million offset by principal payments of $0.4 million on amounts outstanding under the Oxford Loan. Net cash used in financing activities during the six months ended June 30, 2013 was related to principal payments of $2.9 million on amounts outstanding under the Oxford Loan and $1.0 million of capitalized deferred financing costs.

Going Concern

We have incurred losses in each year since our inception in 2002. Our net losses were approximately $14.2 million and $21.2 million for the years ended December 31, 2011 and 2012, respectively and $10.2 million and $2.8 million for the six months ended June 30, 2012 and 2013, respectively. As of June 30, 2013, we had an accumulated deficit of approximately $76.5 million. Our working capital deficit was $4.0 million at June 30, 2013 and we utilized $2.1 million to fund our operations during the six months ended June 30, 2013. Substantially all of our operating losses resulted from expenses incurred in connection with our research programs and from general and administrative costs associated with our operations. We anticipate that we will continue to incur net losses for at least the next several years.

As of June 30, 2013, substantial doubt exists over our ability to continue as a going concern. As of June 30, 2013, we had cash of $3.6 million, accounts payable and accrued expenses of $4.0 million and we owe $9.3 million on our outstanding promissory notes. We expect to have sufficient cash to fund operations for current commitments, assuming the exclusion of the amounts due to Oxford, into September 2013. If we are unable to obtain financing prior to September 30, 2013, we will need to consider the possibility of ceasing operations entirely. In an effort to reduce our cash burn, on July 31, 2013, we entered into a second amendment to the Oxford Loan which authorized us to make an interest only payment on August 1, 2013 on our outstanding promissory note balance. We will resume making principal and interest payments on September 1, 2013 in accordance with the terms of the second amendment. We may enter into a future amendment to defer principal payments with Oxford in an effort to extend our cash runway, but we cannot guarantee that we will be able to enter into such an amendment. Future financing will be required prior to the initiation of our first Phase 3 clinical trial which we plan to initiate in the second half of 2013, assuming we obtain additional financing. We may obtain additional financing in the future through the issuance of our securities in this public offering or another public or private financing, the issuance of debt instruments and/or through a drug development partnership with a biotechnology or pharmaceutical company. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. As we continue to incur losses, our transition to profitability is dependent upon the successful development, approval, and commercialization of our product candidate and achieving a level of revenue adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital.

Future Operations

We have devoted substantial resources to developing PRX302, protecting and enhancing our intellectual property estate and providing general and administrative support for these activities. We have not generated any revenue from product sales and, to date, have funded our operations primarily through public and private equity security sales, a debt financing and an upfront payment from Kissei.

We expect that the net proceeds from this offering and our existing cash, together with interest thereon, will be sufficient to fund our operations through 2015, including through receipt of topline data from our first Phase 3 clinical trial. We will require significant additional financing in the future to fund our operations beyond that timeframe. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. If we are unable to raise sufficient additional capital, we may need to substantially curtail our planned operations. In any event, we expect that we will require additional capital to complete development of PRX302, including completion of both of our planned Phase 3 clinical trials, to obtain regulatory approval of and to commercialize PRX302.

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Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- progress in, and the costs of, our clinical trials, preclinical studies and other research and development activities for PRX302;
- the costs and timing of regulatory approvals;
- our ability to maintain our strategic license with Kissei and its ability to achieve applicable milestones and establish and maintain additional strategic collaborations, including licensing and other arrangements;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of obtaining and securing manufacturing supply for clinical or commercial production of product candidates; and
- the costs of establishing, or contracting for, sales and marketing capabilities if we obtain regulatory approvals to market PRX302.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through private and public sales of our securities, debt financings, by establishing additional strategic collaborations for PRX302 or from exercise of outstanding common share purchase warrants and stock options.

Contractual Obligations and Commitments

The following is a summary of our contractual obligations as of June 30, 2013 (in thousands):

		Payments due by period			
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligation relating to facility[1]	$ 185	$ 185	$	$	$
Principal and interest payable under promissory notes [2]	10,333	6,764	3,569		
Purchase commitments[3]	1,564	1,564			
Total	$ 12,082	$ 8,513	$ 3,569	$	$

(1) We currently lease an office facility comprising our headquarters in San Diego, California under a non-cancelable lease. The lease, as amended, expires in May 2014 and the minimum rent is $12,740 per month, subject to annual cost of living increases, plus our pro rata share of certain operating costs and other expenses. We rent a second facility in Vancouver, British Columbia under a non-cancelable office service agreement. The agreement, as amended, expires in December 2013 and the rent is approximately CND$3,744 per month, or $3,588 per month, as converted, subject to annual cost of living increases.

(2) In July 2011, we entered into the Oxford Loan agreement, which was amended in January 2013 and again in July 2013. Under the terms of the Oxford Loan, we made interest only payments for nine months at a fixed rate of 9.5%. Subsequent to the interest only payments, the note will amortize with principal and interest payments due through the remaining term of the Oxford Loan. The loan term, including interest only period, is 39 months; however, the loan can be prepaid subject to certain provisions and prepayment fees. Upon final repayment of the Oxford Loan on the maturity date, by prepayment, or upon acceleration of the Oxford Loan, we also must make an additional final payment of $0.8 million.

(3) We are required to schedule our manufacturing activities in advance. If we cancel any of these scheduled activities without proper notice we could be required to pay penalties equal to the cost of the originally scheduled activity. As such we have included the activities currently scheduled which, if cancelled, could result in us incurring penalties for cancellation.

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Exclusive License Agreements

We have entered into an exclusive license agreement with UVIC and Johns Hopkins with respect to the use of PRX302 for the development of therapeutics for BPH and other non-cancer diseases and conditions of the prostate. Under this agreement we are required to make payments based upon the achievement of specific development and regulatory milestones separated among 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. As the timing of when these payments will actually be made is uncertain and the payments are contingent upon the completion of future activities, we have excluded these potential payments from the contractual obligations table above. 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, 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%.

Off-balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as defined by applicable SEC regulations) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Related Party Transactions

For a description of our related party transactions, see Certain Relationships and Related Party Transactions.

Changes in and Disagreements with Accountants on Accounting and Financial Disclosures

Following the transition of our Corporate headquarters from Vancouver, British Columbia to San Diego, California, and in anticipation of the commencement of our initial public offering in the United States, with the assistance of the audit committee of our board of directors, we re-evaluated the appointment of our independent registered public accounting firm. As such, on January 10, 2013, PricewaterhouseCoopers LLP (Canada), or PwC Canada, resigned from acting as our independent registered public accounting firm.

The report of PwC Canada on the financial statements for the year ended December 31, 2011 contained an explanatory paragraph regarding our history of significant recurring operating losses and negative cash flows from operations since inception.

During the years ended December 31, 2010 and 2011 and the period from January 1, 2012 through January 10, 2013, there were no disagreements with PwC Canada on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of PwC Canada would have caused them to make reference to the subject matter of the disagreements in connection with its reports on our financial statements for such years.

During the years ended December 31, 2010 and 2011, and the subsequent period from January 1, 2012 through January 10, 2013, there were no reportable events as defined in Item 304(a)(1)(v) of Regulation S-K.

PwC Canada was provided with a copy of the above statements and we requested that it furnish us a letter addressed to the SEC stating whether or not it agrees with the above statements. A copy of PwC Canada s letter is included as an exhibit to this registration statement.

On January 10, 2013, with the approval of the audit committee of our board of directors, we engaged PricewaterhouseCoopers LLP (U.S), or PwC U.S., as our new independent registered public accounting firm. During the year ended December 31, 2010 and 2011, and the subsequent period from January 1, 2013 through January 10, 2013, neither we nor anyone on our behalf consulted PwC U.S. regarding either (1) the application of

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accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on our consolidated financial statements, or (2) any matter that was a disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K, or a reportable event, as that term is defined in Item 304(a)(1)(v) of Regulation S-K. PwC U.S. has reported on our consolidated financial statements for the fiscal year ended December 31, 2012.

Quantitative and Qualitative Disclosure About Market Risk

Our primary market risk is the exposure to foreign currency exchange rate fluctuations. This risk arises from our holdings of foreign currency denominated cash and accounts payable. Changes in foreign currency exchange rates can create significant foreign exchange gains or losses to us. Our current foreign currency risk is primarily with the Canadian dollar as a majority of the expenses incurred by us are denominated in the U.S. dollar. As of June 30, 2013, we had CND$1.1 million, or $1.1 million, as converted, Canadian dollars on hand. A 10% change in the underlying exchange rate would result in a change of $0.1 million of total cash on hand at June 30, 2013. We have minimal direct exposure to interest rate risks as we do not have variable rate financial liabilities. In addition, the Oxford Loan has a fixed interest rate of 9.5% therefore fluctuations in interest rates do not have an effect the total amount due on the outstanding principal.

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

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

We expect to initiate in the second half of 2013 the first of two planned Phase 3 clinical trials of PRX302 for the treatment of the symptoms of BPH. Based on feedback from our guidance meeting with the FDA in February 2013, we expect to enroll approximately 440 patients in this Phase 3 clinical trial. This Phase 3 clinical trial will use the IPSS outcome measure evaluated at 12 months as the primary endpoint, which is consistent with clinical trials of another injectable currently under development for the treatment of the symptoms of BPH. Assuming sufficient capital resources, we plan to commence our second Phase 3 clinical trial following a blinded interim analysis by an independent data monitoring committee conducted once all patients have completed three months in the first Phase 3 clinical trial, which analysis we expect to occur by the end of 2014.

Background on BPH

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

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Current Therapies for BPH

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

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

Oral Drug Therapy

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

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

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

Minimally Invasive Surgical Therapies

Minimally invasive surgical therapies used to treat the symptoms of BPH include transurethral microwave thermotherapy, or TUMT, transurethral needle ablation, or TUNA, and green laser treatment, which delivers high

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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 still 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 and clinical results to date suggest it is safer and better tolerated than existing therapies. It is delivered through a targeted injection into the prostate, precisely ablating the prostate tissue without damaging neighboring tissue and nerves. This method of administration limits the circulation of the drug in the body and we believe that this limited systemic exposure to the drug, together with how the drug is activated in the body, greatly diminishes the risk of side effects. In our Phase 2b clinical trial, PRX302 has been shown to significantly improve symptoms of BPH through 12 months of follow-up after a single treatment.

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

PRX302 Transrectal Administration Schematic

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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.

PRX302- Mechanism of Action

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

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

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The mechanism of action is shown in the figure below.

PRX302 Mechanism of Action

Clinical Overview

To date, we have conducted six clinical trials of PRX302. Four of these clinical trials were for the treatment of the symptoms of BPH and two were for the treatment of prostate cancer. A total of 126 patients with moderate to severe BPH symptoms and 30 patients with prostate cancer have been treated with PRX302, for a combined PRX302 exposure of 156 patients. In each of the six trials, patients were monitored for 12 months following a single treatment of PRX302.

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

In clinical trials, patients with BPH, PRX302 has consistently shown clinically meaningful, sustained efficacy with regard to improvement in LUTS, as measured by IPSS and Qmax, the standard measures of the treatment of symptoms for BPH. PRX302 has been well-tolerated in all clinical studies to date. Adverse events were typically mild and transient in nature, limited to local discomfort and irritative urinary symptoms that generally occur during the first four days after injection. There were no drug-related erectile dysfunction or cardiovascular side effects reported.

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

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Clinical Development in BPH

Our clinical program for PRX302 is summarized below.

Completed or Ongoing Clinical Development

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

Planned Clinical Development

CLINICAL TRIAL	STATUS	TRIAL DESIGN
PLUS-1	Anticipated initiation of enrollment in the second half of 2013	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		
		440 patients
		Dosing: 0.6µg/g
		Volume: 20% of prostate volume
Phase 3 Trial #2		Prospective, randomized, double-blind, placebo-controlled clinical trial of a single transrectal intraprostatic treatment of PRX302
		Dosing: TBD
		Volume: 20% of prostate volume
Open-Label Safety Study		Safety of repeat dose and long-term safety of transrectal intraprostatic treatment of PRX302
Phase 3		
		Approximately 100 patients
		Dosing: TBD
		Volume: 20% of prostate volume

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

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

The results of this clinical trial were:

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

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

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 ³5% 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.

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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.

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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 six 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.

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Plans For Future Clinical Development

We expect to initiate in the second half of 2013 the first of two Phase 3 clinical trials of PRX302 for treatment of the symptoms of BPH, which trial we sometimes refer to as PLUS-1. Based on feedback from our guidance meeting with the FDA in February 2013, we expect to enroll approximately 440 patients in this Phase 3 clinical trial. Our plan is that the first Phase 3 clinical trial will be a randomized, double-blind, dose confirmation, multicenter, vehicle-controlled clinical trial to confirm the efficacy and safety of a single treatment of PRX302 transrectally administered in patients with moderate to severe LUTS due to BPH. This multicenter, multinational clinical trial will randomize patients across as many as 100 clinical trial sites to one of two treatment groups. The primary outcome measure is the change from baseline in IPSS, which is the outcome measure that has been used in previous clinical trials of PRX302 and for the regulatory approval of oral medications for treatment of the symptoms of BPH as well as MIST procedures. This change from baseline will be evaluated at 12 months, which time frame is consistent with clinical trials of another injectable currently under development for the treatment of the symptoms of BPH. Secondary outcome measures will include an improvement in Qmax. In this first Phase 3 clinical trial, we intend to have an independent data monitoring committee conduct a blinded interim analysis once all patients have completed three months of treatment to assess safety and treatment effect. Assuming sufficient capital resources, we plan to commence our second Phase 3 clinical trial following this analysis, which we expect to occur by the end of 2014.

To date, no patients have been administered more than one treatment of PRX302. Assuming sufficient capital resources, we are planning to initiate an open label repeat dose clinical trial before the end of 2014, 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, 12 months after their first dose. We believe the planned 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

Phase 2 Open-Label Clinical Trial in Prostate Cancer

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

While our current development of PRX302 is focused on the treatment of the symptoms of BPH, based on the results of this clinical trial, we will continue to evaluate future development in prostate cancer.

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.

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Our Strategy

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

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

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

Evaluate further development of PRX302 in prostate cancer. Our current development of PRX302 is focused on the treatment of the symptoms of BPH. We will continue to evaluate future development of PRX302 in prostate cancer.

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, 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. Nymox Pharmaceutical Corporation s injectable NX-1207 is currently in Phase 3 clinical trials for the treatment of the symptoms of BPH. Light Sciences Oncology Inc. s Aptocine™ is currently in Phase 2 clinical trials for the treatment of the symptoms of BPH. NeoTract, Inc. is currently in late clinical stage evaluation of their minimally invasive device Urolift, which is designed to open the urethra directly without the need to resect or ablate prostate tissue.

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Sales and Marketing

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

Specifically, we intend to:

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

Manufacturing

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

There has been a successful transfer of the technology for both the production and release of PRX302 from Dompé to BI and scale-up up to the commercial batch size is underway and should be complete by the end of 2013. This full scale commercial batch will be used to supply drug product for the second Phase 3 clinical trial. Although PRX302 is manufactured from readily available materials using standard pharmaceutical methods and equipment, any replacement of BI as our manufacturer may lead to significant delays and increase our costs.

Boehringer Ingelheim RCV GmbH & Co KG

In June 2012, we entered into a technology transfer and supply agreement with BI, for the provision of technology transfer services and for the establishment of certain manufacturing processes for, and the manufacture of, purified PRX302, the diluting agent for use in PRX302 drug products and placebos, and a placebo to be used in clinical trials. We will be required to make payments based upon the provision and completion of certain tasks specified in the agreement. Starting in 2013, the prices of BI s services will be adjusted annually based on the average of the Austrian trade index and the average Standard Wages Index, both as of July of the previous year, subject to certain restrictions. BI will be required to manufacture the products in line with certain project timelines. If we postpone the performance of any services, we may be required to pay certain postponement fees. Additionally, if we cancel any services we will be required to pay the entire cost for such services and the entire cost of any materials that cannot be returned by BI to the appropriate vendor or otherwise used by BI. If we are required to have any product manufactured outside our expected manufacturing cycles due to an unforeseen loss of product, we will have to work with BI to arrange an available manufacturing

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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 five patent families:

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

We own or have exclusively licensed four issued United States patents related to our prostate program: US 7838266 (prostate cancer) expiring in 2022, US 7282476 (prostate cancer) expiring in 2023, US 7745395 (prostate cancer) expiring in 2023, and US 8278279 (prostatitis) expiring in 2029, as well as 6 issued patents in countries including Australia, China, the European Patent Office (including 17 extension states), India, Japan, and South Africa expiring in 2022, 8 patents in the European Patent Office (including 14 extension states), Japan, China, Australia, New Zealand, Israel, Singapore, and South Africa expiring in 2026, and 17 additional pending U.S. and/or foreign patent applications in Australia, Canada, the European Patent Office, India, Japan, and South Korea variously set to expire in 2022, 2026, 2029, or 2031. This portfolio includes issued U.S. patents that cover the composition of PRX302 or methods of using PRX302 to treat prostatitis or prostate cancer, as well as a pending U.S. patent application that covers the method of using PRX302 to treat the symptoms of BPH. This portfolio includes two issued Chinese patents. To date, we have not sought to enforce any issued patents in

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China. We cannot give any assurances that we will be able to enforce our patents in China to the same degree that we could in the United States.

Technology Licenses

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

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

In order to secure the license, we paid an initial license fee of CND$45 thousand, or $39 thousand, 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

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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 thousand, or $62 thousand, applying the conversion rate as of the date of payment, and a reimbursement fee of CND$28 thousand, or $24 thousand, 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 six months ended June 30, 2013, we recorded as revenue a $5.0 million non-refundable milestone payment due from Kissei upon the achievement of certain development activities. We received payment for the milestone in April 2013. In addition, we remain eligible to receive up to approximately $67.0 million in additional payments contingent upon achievement of specified development, regulatory and commercial milestones, some of which are in Kissei s sole discretion to achieve, separated among the indications of BPH, prostate cancer, and prostatitis or other diseases of the prostate, as well as the achievement of overall accumulated gross sales levels for such indications. The additional $67.0 million of non-refundable milestone payments is comprised as follows: aggregate milestone payments of $12.0 million are related to the BPH indication, of which $7.0 million relates to the completion of regulatory approvals and $5.0 million relates to the achievement of certain product sale goals; a total of $21.0 million is related to the prostate cancer indication, of which $7.0 million relates to the completion of development activities, $7.0 million relates to the completion of regulatory approvals and $7.0 million relates to the achievement of certain product sale goals; and a total of $21.0 million is related to prostatitis or other diseases of the prostate, of which $7.0 million relates to the completion of development activities, $7.0 million relates to

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

- completion of preclinical laboratory tests, animal studies and formulation studies performed in accordance with the FDA s current Good Laboratory Practices, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials in the United States may begin;
- performance of adequate and well-controlled human clinical trials in accordance with the FDA s current good clinical practices, or GCP, regulations to establish the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of a BLA;

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

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

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

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

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

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

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

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

Phase 3. Clinical trials are undertaken to further evaluate dosage, and provide substantial evidence of clinical efficacy and safety in an expanded patient population (such as several hundred to several thousand) at geographically dispersed clinical trial sites. Phase 3 clinical trials are typically conducted when Phase 2 clinical trials demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile. These trials typically have at least two groups of patients who, in a blinded fashion, receive either the product or a placebo. Phase 3 clinical trials are intended to establish the

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overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

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

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

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

U.S. Review and Approval Processes

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

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

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

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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 Fraud and Abuse Laws

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

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply

to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not satisfy the requirements of an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

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

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

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;
- new requirements to report certain financial arrangements with physicians and others, including reporting any transfer of value made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for

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prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and

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

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

Europe / Rest of World Government Regulation

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

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

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

Employees

As of August 1, 2013, we had eight full-time employees, four of whom have Ph.D. or M.D. degrees, and one part-time employee. None of our employees are covered by collective bargaining agreements and we consider relations with our employees to be good.

Facilities

Our corporate headquarters are located in San Diego, California. The facility we lease encompasses approximately 3,062 square feet of office space. The lease for this facility expires in May 2014. 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.

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Corporate Structure and Facilities

Our predecessor, Protox Pharmaceuticals Inc. was incorporated in January 2002. Sophiris was formed in May 2003 under the predecessor to the Business Corporations Act (British Columbia), 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 its name to Protox Therapeutics Inc. In January 2005, the company 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 senior management. In connection with this operational realignment, we changed our name to Sophiris Bio Inc., effective as of April 2, 2012.

Our principal executive office and is at 1258 Prospect Street, La Jolla, California 92037. Our telephone number is (858) 777-1760 and our facsimile number is (858) 412-5693. Our registered and records office is located 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 web site is not part of this prospectus.

We have one wholly-owned subsidiary, Sophiris Bio Corp., which was incorporated March 29, 2011 under the laws of the State of Delaware, and one indirect subsidiary, Sophiris Bio Holding Corp., which is wholly-owned by Sophiris Bio Corp. and which was incorporated December 21, 2012 under the laws of the State of Delaware.

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MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information regarding our executive officers and directors as of August 1, 2013:

Name	Age	Position(s)
Executive Officers		
Randall E. Woods	61	Chief Executive Officer, President and Director
Allison Hulme, Ph.D.	50	Chief Operating Officer and Head of Research and Development
Peter Slover	38	Chief Financial Officer
Non-Employee Directors		
Lars Ekman, M.D., Ph.D.	63	Executive Chairman and Director
John (Jack) Geltosky, Ph.D.	68	Director[(1)(2)(3)]
Jim Heppell	57	Director[(1)(2)(3)]
William R. Rohn	69	Director[(1)]
Joseph T. Turner	61	Director[(4)]

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the corporate governance and nomination committee.
(4) Mr. Turner s appointment as a director will be effective upon the effectiveness of the registration statement of which this prospectus is a part.

Executive Officers

Randall E. Woods, Chief Executive Officer and President

Mr. Woods has been our Chief Executive Officer and President since August 2012 and a member of our board of directors, or Board, since October 2012 and brings with him 40 years of biotech and pharmaceutical leadership experience. Prior to joining Sophiris, Mr. Woods was serving as a consultant to a number of private biotechnology companies. From September 2007 until September 2011, Mr. Woods was President and Chief Executive Officer of Sequel Pharmaceuticals, a private biotechnology company. Mr. Woods was the President and Chief Executive Officer of NovaCardia, Inc., a pharmaceutical company focused on cardiovascular diseases, until its acquisition by Merck & Co. From May 1996 until July 2003 and prior to NovaCardia, Mr. Woods was President and Chief Executive Officer of Corvas International, Inc., a publicly held biopharmaceutical company focused on cardiovascular disease and cancer, until its acquisition by Dendreon Corporation in July 2003. Before joining Corvas, he served as President of Boehringer Mannheim s U.S. pharmaceutical operations from March 1994 until March 1996 and was Vice President of marketing and sales at Boehringer Mannheim from December 1993 to February 1994. Prior to that he spent 20 years at Eli Lilly & Company, a pharmaceutical company, in various sales and marketing positions from 1973 to December 1993. Mr. Woods is a past Chairman for the advisory board of UC San Diego s Sulpizio Family Cardiovascular Center and is a past Chairman of the Board of Directors for BIOCOM, a life science industry association in Southern California. Mr. Woods serves on the Board of Arena Pharmaceuticals and is Chairman of the Board for Sorbent Therapeutics. He received his B.S. in Biology and Chemistry from Ball State University and an MBA in Marketing from Western Michigan University. Based on Mr. Woods expertise and extensive experience in biotechnology and service as our Chief Executive Officer and President, the Board believes Mr. Woods has the appropriate set of skills to serve on our Board.

Dr. Allison Hulme, Chief Operating Officer and Head of Research and Development

Dr. Hulme has been our Chief Operating Officer and Head of Research and Development since April 2011, and she brings over 20 years of drug development experience to the company. From January 2005 to October

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2009, Dr. Hulme served as Executive Vice President of Autoimmune, Tysabri, Global Development and Head of Autoimmune and Tysabri Franchise at Elan Corporation, plc (also known as Elan Pharmaceuticals), a neuroscience-focused biotechnology company. She served as Executive Vice President and head of global development at Elan Pharmaceuticals from October 1995 to January 2005. Previously, Dr. Hulme held several positions in clinical research at Glaxo Wellcome Pharmaceuticals and served as lecturer at Luton University. Dr. Hulme holds a first class honors Degree in Science from Luton University and a Ph.D. from Cranfield Institute of Technology.

Peter T. Slover, Chief Financial Officer

Mr. Slover has been our Chief Financial Officer since January 2013. He served as our Head of Finance and Principal Accounting Officer from April 2012 to January 2013. From April 2004 to April 2012, Mr. Slover held a variety of significant management positions at Anadys Pharmaceuticals, Inc., a public biotechnology company, including Vice President, Finance and Operations, a position that he held from July 2009 to April 2012, Senior Director, Finance and Corporate Controller, Senior Manager, Financial Reporting and Internal Controls and Manager of Financial Reporting. Prior to joining Anadys, Mr. Slover was an auditor at KPMG LLP, where he spent seven years in public accounting. Mr. Slover is a Certified Public Accountant in the State of California. He received a B.S. degree in Business Administration from Shippensburg University.

Non-Employee Directors

Dr. Lars Ekman, Executive Chairman

Dr. Ekman has been our Executive Chairman since April 2011 and a member of our Board since November 2010. He served as our President from April 2011 to August 2012. Dr. Ekman also currently serves as an executive partner of Sofinnova Ventures, a venture capital fund, a position he has held since April 2008. From January 2001 to December 2007, Dr. Ekman was Executive Vice President and President of Research & Development at Elan Pharmaceuticals, a neuroscience-focused biotechnology company. Prior to joining Elan, Dr. Ekman was Executive Vice President, Research and Development at Schwartz Pharma AG, a biopharmaceutical company, from February 1997 to January 2001. Prior to joining Schwartz, Dr. Ekman served in various senior executive roles at Pharmacia (now Pfizer), a pharmaceutical company, for over 16 years. Dr. Ekman is a director of Prothena Biosciences Limited, Amarin Corporation plc, InterMune Inc., and two private companies, Ocera Therapeutics, Inc. and Cebix Incorporated. Dr. Ekman is a board certified surgeon with a Ph.D. in experimental biology. He obtained his Ph.D. and M.D. from the University of Gothenburg, Sweden. Based on Dr. Ekman s senior management experience in the biopharmaceutical industry, his scientific background and his knowledge of and perspective on the company, the Board believes Dr. Ekman has the appropriate set of skills to serve on our Board.

Dr. John (Jack) Geltosky, Director

Dr. Geltosky has served on our Board since September 2008. He is currently Managing Director of JEG and Associates, LLC, a business development consultancy firm focused on biotech and pharmaceuticals, a position he has held since September 2011. From October 2007 to September 2011, Dr. Geltosky served as Senior Vice President of Business Development for Arizona Technology Enterprises, the technology transfer arm of Arizona State University. Prior to Arizona Technology Enterprises, Dr. Geltosky was Vice President of External Science, Technology and Licensing at Bristol Myers Squibb, or BMS, a public pharmaceuticals company, where he was responsible for the acquisition and licensing of, as well as coordinating due diligence efforts on, potential in- and out-licensing candidates. Prior to joining BMS, Dr. Geltosky was President and Chief Executive Officer of Message Pharmaceuticals, Inc., a pharmaceutical company. Prior to Message Pharmaceuticals, he was Vice President, Scientific Licensing, Worldwide Business Development at SmithKline Beecham (now GlaxoSmithKline). For 10 years, Dr. Geltosky held roles of increasing responsibility within Johnson & Johnson. Dr. Geltosky began his career as a research scientist at E.I. DuPont. Dr. Geltosky holds a B.S. in chemistry from

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Memphis State University and a Ph.D. in biochemistry from the California Institute of Technology. Based on Dr. Geltosky s senior management experience in the biotechnology industry and his scientific background as well as his experience evaluating drug candidates, the Board believes Dr. Geltosky has the appropriate set of skills to serve on our Board.

Jim Heppell, Director

Mr. Heppell was our founding Chief Executive Officer and President and has served on our Board since May 2003. He is President of BC Advantage Funds (VCC) Ltd., a venture capital corporation located in British Columbia, a position he has held since July 2005. Prior to his involvement with BC Advantage Funds, Mr. Heppell was co-founder, Chief Executive Officer and Fund Manager of the Advantage Life Science Fund I. Mr. Heppell is a director of BC Advantage Funds (VCC) Ltd. and Venturi Ventures Inc., a medical device firm, and Chairman or director of a number of private life science companies. Previously, Mr. Heppell was Chairman of Inovio Biomedical Corp., a public biotechnology company. Mr. Heppell has a B.Sc. degree in Microbiology and an LL.B. from the University of British Columbia. Based on Mr. Heppell s experience investing in and building life science companies as well as his experience serving on the boards of other public and private life science companies, the Board believes Mr. Heppell has the appropriate set of skills to serve on our Board.

William R. Rohn, Director

Mr. Rohn has served on our Board since February 2011. He has over 35 years of experience as a senior executive in the pharmaceutical and biotech industry. Mr. Rohn retired in January of 2005 from the position of Chief Operating Officer at Biogen-Idec, a global biotechnology company. Prior to that position, Mr. Rohn was the President and chief operating officer of IDEC Pharmaceuticals, a biopharmaceutical company, from January 1999 to November 2003. Mr. Rohn spent approximately 25 years in the pharmaceutical sector in a variety of commercial operating roles of increasing responsibilities at Abbott Laboratories, Bristol-Myers Squibb Co. and Adria Laboratories (now part of Pfizer). Mr. Rohn serves on the Board of Directors of Cebix Incorporated and Hansen Medical, and was previously a director at Cerus Corp., Elan Corporation plc, Metabasis Therapeutics Inc. and Pharmacyclics, Inc. Mr. Rohn received a B.A. Degree in Marketing from Michigan State University. Based on Mr. Rohn s senior management experience in the biopharmaceutical industry and his extensive experience working in the pharmaceutical sector, the Board believes Mr. Rohn has the appropriate set of skills to serve on our Board.

Joseph L. Turner, Director

Mr. Turner has been appointed to become a member of our Board upon the effectiveness of the registration statement of which this prospectus is a part. Mr. Turner retired from active employment in 2006 and currently serves on the board of directors of several companies. Beginning in 1999, Mr. Turner served as the Chief Financial Officer at Myogen, Inc., a pharmaceutical company, until the sale of the company to Gilead Sciences in 2006. Prior to that experience, from 1997 to 1999, Mr. Turner served as Vice President of Finance at Centaur Pharmaceuticals, a pharmaceutical company, and from 1992 to 1997, Mr. Turner served as Vice President of Finance at Cortech, Inc., a biopharmaceutical company. Mr Turner has also served in other finance roles including Director of Finance, Eli Lilly and Company (Switzerland), a biopharmaceutical company, and Treasurer, Eli Lilly and Company (Switzerland). He serves on the boards of four pharmaceutical companies: Kythera Biopharmaceuticals Inc., Alexza Pharmaceuticals, Inc., Corcept Therapeutics, Inc. and BioClin Therapeutics, Inc. Previously, he has served on the boards of NovaCardia, Inc., Sequel Pharmaceuticals, ApoLogic Inc., SGX Pharmaceuticals, Allos Therapeutics, Inc, and QLT Inc. Mr Turner received a B.A. in Chemistry from Swarthmore College, an M.A. in Molecular Biology from the University of Colorado at Boulder and an M.B.A. from the University of North Carolina at Chapel Hill. The Board believes that Mr. Turner possesses specific attributes that qualify him to serve on our Board, including his years of experience in the biotech and pharmaceutical industries and his finance experience.

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Board Composition

Our business and affairs are organized under the direction of our Board, which currently consists of five members. The primary responsibilities of our Board are:

- the adoption of a strategic planning process and the approval and review, at least annually, of our strategic business plan proposed by management, including a statement of vision, mission and values, and to adopt such a plan with such changes as the Board deems appropriate;
- the identification of the principal risks of our business and overseeing the implementation of appropriate systems to manage these risks;
- succession planning, including appointing, training and monitoring senior management and, in particular, the CEO;
- overseeing the integrity of members of management and a culture of integrity throughout the company; and
- overseeing the development and application of our internal control and management information systems.

The Board meets on a quarterly basis and more frequently as required. During 2011, the Board met nine times. In addition, informal communications between management and directors occur apart from regularly scheduled Board and committee meetings.

At each annual meeting of shareholders of the company, the entire Board of Directors retires and directors are elected for the next term. Each director serves until the close of the next annual meeting of shareholders or until his or her successor is elected or appointed, unless his or her office is earlier vacated in accordance with our articles or with the provisions of the BCBCA.

Our Board has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our Board has determined that two of our five directors, Dr. Geltosky and Mr. Rohn, are independent directors, as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules. Our Board has determined that Mr. Turner, upon the effective date of his appointment to our Board, will be an independent director, as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules. Accordingly, upon the effectiveness of the registration statement of which this prospectus is a part, three out of our six directors will be independent. Pursuant to NASDAQ Marketplace Rule 5615(b)(1), within a year of the effectiveness of the registration statement of which this prospectus is a part, our Board must be comprised of a majority of independent directors. We intend to be in compliance with these rules within a year of the effectiveness of the registration statement of which this prospectus is a part by increasing the number of independent directors and/or decreasing the number of non-independent directors.

Board Leadership Structure

Our Board is currently chaired by our Executive Chairman, Lars Ekman. Dr. Ekman served as our President from April 2011 to August 2012 and is therefore not independent. On a regular basis, the directors, other than those who are also members of management, are given an opportunity to meet privately. At a minimum, the Board meets quarterly without the presence of employee-directors.

Role of the Board in Risk Oversight

One of the key functions of our Board is informed oversight of our risk management process. The Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through various standing committees of our Board that address risks inherent in their respective areas of oversight. In particular, our Board is responsible for monitoring and assessing

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strategic risk exposure and our audit committee is responsible for considering and discussing our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our corporate governance and nomination committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Board Committees

Our Board has established an audit committee, a compensation committee and a corporate governance and nomination committee.

Audit Committee

Our audit committee currently consists of Messrs. Rohn (chair), Geltosky and Heppell. Under Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, we are permitted to phase in our compliance with the independent audit committee requirements set forth in NASDAQ Marketplace Rule 5605(c) and Rule 10A-3 under the Exchange Act as follows: (1) one independent member at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing. Our board of directors has determined that each of Messrs. Rohn (chair) and Geltosky are independent directors under NASDAQ Marketplace Rules and under Rule 10A-3 under the Exchange Act. Within one year of our listing on the NASDAQ Global Market, we expect that Mr. Heppell will have resigned from our audit committee and that any new directors added to the audit committee will be independent under NASDAQ Marketplace Rules and Rule 10A-3. Each member of our audit committee can read and understand fundamental financial statements in accordance with NASDAQ audit committee requirements and is financially literate, as required by Canadian securities laws. In arriving at this determination, the board has examined each audit committee member s scope of experience and the nature of their employment in the corporate finance sector.

The functions of the audit committee, as set out in a written charter adopted by our Board, include:

- recommending the following to the Board of Directors: (i) the external auditor to be nominated for the purpose of preparing or issuing an auditor s report or performing other audit, review or attest services for the company; and (ii) the compensation of the external auditor;
- overseeing the work of the external auditor engaged for the purpose of preparing or issuing an auditor s report or performing other audit, review or attest services for the company, including the resolution of disagreements between management and the external auditor regarding financial reporting;
- pre-approving all non-audit services to be provided to the company or its subsidiary entities by our external auditor in accordance with the pre-approval process noted below;
- reviewing our financial statements, management s discussion and analysis of financial condition and results of operations and annual and interim earnings press releases before the company publicly discloses this information;
- ensuring that adequate procedures are in place for the review of our public disclosure of financial information extracted or derived from our financial statements, and must periodically assessing the adequacy of those procedures;
- establishing procedures for: (i) the receipt, retention and treatment of complaints received by the company regarding accounting, internal accounting controls or auditing matters; and (ii) the confidential, anonymous submission by employees of the company of concerns regarding questionable account or auditing matters; and

reviewing and approving our hiring policies regarding partners, employees and former partners and employees of the present and former external auditor of the company.

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Our Board has determined that Mr. Rohn, the audit committee chair, qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the NASDAQ Listing Rules. In making this determination, our board has considered formal education and the nature and scope of experience that he has previously had with public companies. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

Our Board has adopted a written charter for the audit committee that will be available on our website, www.sophirisbio.com, upon the closing of this offering. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

Compensation Committee

Our compensation committee consists of Messrs. Geltosky (chair) and Heppell. Under NASDAQ Marketplace Rule 5615(b)(1), we are permitted to phase in our compliance with the independent compensation committee requirements set forth in NASDAQ Marketplace Rule 5605(d) as follows: (1) one independent member at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing. Our Board has determined that Mr. Geltosky is independent under the NASDAQ listing standards and Canadian securities laws, is a non-employee director as defined in Rule 16b-3 promulgated under the Exchange Act and is an outside director as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended. Within one year of our listing on the NASDAQ Global Market, we expect that Mr. Heppell will have resigned from our compensation committee and that any new directors added to the compensation committee will be independent under NASDAQ Marketplace Rules. The functions of the compensation committee, as set forth in the committee s written charter adopted by our Board, include:

- establishing and monitoring our long-range plans and programs for attracting, retaining, developing and motivating employees;
- reviewing recommendations for the appointment of persons to senior executive positions;
- considering terms of employment and matters of compensation, including assessing the achievement of corporate as well as individual objectives for the purpose of calculating annual cash bonuses and recommending awards under our incentive stock option plan for the CEO and senior executive officers;
- reviewing and approving all employment agreements, separation and severance agreements and other compensatory contracts, arrangements, prerequisites and payments for senior executive officers to ensure such agreements are consistent with our general compensation goals; and
- periodically reviewing our incentive-compensation and equity-based plans and making recommendations to the Board regarding such plans.

Our Board has adopted a written charter for the compensation committee that will be available on our website, www.sophirisbio.com, upon the closing of this offering. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

Corporate Governance and Nomination Committee

Our corporate governance and nomination committee consists of Messrs. Heppell (chair) and Geltosky. Under NASDAQ Marketplace Rule 5615(b)(1), we are permitted to phase in our compliance with the independent nominating and corporate governance committee requirements set forth in NASDAQ Marketplace Rule 5605(e) as follows: (1) one independent member at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing. Our Board has determined that Mr. Geltosky is independent under the NASDAQ listing standards and Canadian securities laws, is a non-employee director as defined in Rule 16b-3 promulgated under the Exchange Act and is an outside director as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended. Within

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one year of our listing on the NASDAQ Global Market, we expect that Mr. Heppell will have resigned from our nominating and corporate governance committee and that any new directors added to the nominating and corporate governance committee will be independent under NASDAQ Marketplace Rules.

The functions of the corporate governance and nomination committee, as set forth in the committee s written charter adopted by our Board, include, among other things:

- nominating a balanced mix of Board members with appropriate experience and expertise who will best serve the interests of the company and enhance shareholder value;
- reviewing director candidates properly submitted by the company s shareholders;
- reviewing and evaluating the Board s committee structure and recommending to the Board for its approval directors qualified to serve as members of each committee;
- regularly reviewing issues and developments related to corporate governance;
- reviewing succession planning;
- assessing the performance of the Board, all committees thereof and individual directors; and
- ensuring that the company s policies on continuous disclosure and communications with analysts are updated as required and are provided to all new directors and senior officers.

Our Board has adopted a written charter for the corporate governance and nomination committee that will be available on our website, www.sophirisbio.com, upon the closing of this offering. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

Compensation Committee Interlocks and Insider Participation

We have established a compensation committee, which has and will make decisions relating to compensation of our executive officers. None of our current or former executive officers serves as a member of the compensation committee. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or Board of any other entity that has one or more executive officers serving as a member of our Board or compensation committee.

Code of Business Conduct and Ethics

We have adopted, effective upon the closing of this offering, a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. Following this offering, a current copy of the code will be available on our website, www.sophirisbio.com. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

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EXECUTIVE AND DIRECTOR COMPENSATION

Our named executive officers, or NEOs, for 2012, which consist of (1) our principal executive officers during 2012, (2) our next two highest compensated executive officers other than the principal executive officer and (3) one former executive officer who would have been included among our highest compensated executive officers but for the fact that he was not serving as an officer at the end of fiscal year 2012, are:

Randall E. Woods, our Chief Executive Officer and President

Dr. Lars Ekman, our Executive Chairman, and formerly, our President

Peter T. Slover, our Chief Financial Officer

Dr. Allison Hulme, our Chief Operating Officer and Head of Research and Development

Alexander Casdin, our former Chief Financial Officer

Summary Compensation Table

The following table sets forth total compensation awarded to, earned by or paid to our NEOs for the last two completed fiscal years.

Name and principal position	Year	Salary ($)[1]	Option awards ($)[2]	Non-equity incentive plan compensation ($)[1][3]	All other compensation ($)[1]	Total compensation ($)[5]
Randall E. Woods[4]	2012	159,375	787,985	71,719[5]	18,487[6]	1,037,566
Chief Executive Officer and President						
Dr. Lars Ekman[7]	2012	60,000				60,000
Executive Chairman and former President	2011	55,272[8]	259,013			314,285
Peter T. Slover[9]	2012	174,292	80,838	62,745[5]	1,286	319,161
Chief Financial Officer						
Dr. Allison Hulme[10]	2012	330,000		148,500[5]	139,786[11]	618,286
Chief Operating Officer and Head of Research and Development	2011	248,558	444,964	124,278	99,672 [12]	917,472
Alexander Casdin[13]	2012	198,333	[14]		81,028[15]	279,361
Former Chief Financial Officer	2011	64,167	114,517	25,666	124	204,474

(1) Except as otherwise indicated, compensation amounts that were paid in Canadian dollars have been converted to U.S dollars for purposes of the table, based on the annual average U.S. dollar per Canadian dollar exchange rate for the applicable year in which the amounts were

paid. The U.S. dollar per Canadian dollar exchange rate used for such conversion is 1.0051 and 0.9891 for 2012 and 2011, respectively.

(2) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during the applicable fiscal year computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718, *Compensation Stock Compensation*, or ASC 718 and excluding the effect of estimated forfeitures. Assumptions used in the calculation of the 2011 amounts are included in Note 13 of the Notes to the Consolidated Financial Statements. The assumptions used in the calculation of the 2012 amounts are as follows: dividend rate 0%, risk-free interest rate 1.2%, expected life of the option term (years) 3.74, volatility 73.0% and forfeiture rate 9.37%. The aggregate grant date fair value of the performance-based options granted to Dr. Ekman, Dr. Hulme and Mr. Casdin in 2011 and to Mr. Slover in 2012 is calculated based upon the probable outcome of the performance conditions (assuming achievement of the highest level of performance conditions), consistent with the estimate of aggregate compensation cost to be recognized over the service period determined as of the grant date under ASC 718, excluding the effect of estimated forfeitures. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options or the sale of the common shares underlying such stock options. The exercise price for

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stock option awards granted to the named executive officers were denominated in Canadian dollars on the date of the grant and were converted to U.S. dollars using the U.S. dollar per Canadian dollar exchange rate on the date of grant of the stock option, as indicated in the Outstanding Equity Awards at Fiscal Year End table below. The U.S. dollar per Canadian dollar exchange rates used for such conversion were 1.012, 1.0036, 0.9814, 1.0275 and 1.0147 for the October 4, 2012, April 4, 2012, October 11, 2011, June 9, 2011 and February 16, 2011 option grant dates, respectively.

(3) Amounts shown represent performance bonuses earned for the applicable fiscal year.

(4) Mr. Woods was hired effective August 16, 2012. The salary above reflects the prorated portion earned from Mr. Wood s hire date through December 31, 2012.

(5) As of the date of the filing of this prospectus, performance bonuses have not been paid for 2012. The Board authorized the payment of the bonuses upon the completion of a successful financing or strategic transaction as described below under the section Annual Performance-Based Bonus Opportunity.

(6) Includes: (i) $5,460, which represents payments made by the company to Mr. Woods for medical insurance, in lieu of providing Mr. Woods medical benefits, (ii) $4,604, which represents a gross-up payment to Mr. Woods for applicable federal and state taxes related to the payments for such insurance (iii) $6,375 of matching contributions paid under the terms of our 401(k) plan and (iv) the value of company paid premiums of $708 for life, accidental death and dismemberment and long-term disability insurance in excess of Internal Revenue Service limits and $1,340 as a gross up payment for applicable federal and state taxes related to such premiums.

(7) On April 18, 2011, Dr. Ekman was formally appointed as the company s Chairman and President. As the Chairman, Dr. Ekman received an annual cash retainer of $45,000 and a stock option grant covering 1,730 shares pursuant to our non-employee director compensation program. As President, Dr. Ekman received an increase of $15,000 in his annual cash retainer and stock option grants covering 11,538 shares. Dr. Ekman stepped down in his role as our President upon Mr. Woods commencement of employment as our Chief Executive Officer and President on August 16, 2012.

(8) Reflects compensation for Dr. Ekman s services as our President as well as his cash retainer for his Board services. Dr. Ekman received several compensation payments in Canadian dollars, which have been converted to U.S. dollars using a U.S. dollar per Canadian dollar exchange rates of 0.9766 and 1.0346 for the first and second quarters of 2011, respectively. Dr. Ekman s quarterly compensation payments for the third and fourth quarter of 2011 and for 2012 were paid in U.S. dollars.

(9) Mr. Slover was hired effective April 4, 2012 as our Head of Finance and Principal Accounting Officer and became our Chief Financial Officer effective January 10, 2013. The salary and non-equity incentive plan payment above reflect the prorated portion earned from Mr. Slover s hire date through December 31, 2012.

(10) Dr. Hulme was hired effective March 31, 2011. The salary and non-equity incentive plan payment above for 2011 reflect the prorated portion earned from Dr. Hulme s hire date through December 31, 2011.

(11) Includes reimbursed commuting costs for Dr. Hulme s travel from her residence to San Diego. Includes reasonable expenses for temporary housing, airfare and car service while Dr. Hulme is living in San Diego. All commuting reimbursement amounts are grossed up for applicable federal and state taxes. The table below outlines the costs reimbursed and related tax gross-ups during 2012:

Type of expenses reimbursed	Expense	Gross-up on Reimbursed Expense	Total
Temporary Housing	$ 44,400	$ 33,563	$ 77,963
Airfare	16,849	12,836	29,685
Car Service	12,016	9,154	21,170
Total			$ 128,818

Also included as a component of other compensation is $8,700 of matching contributions paid under the terms of our 401(k) plan, the value of company paid premiums of $1,602 for life, accidental death and dismemberment and long-term disability insurance in excess of Internal Revenue Service limits and $666 as a gross up payment for applicable federal and state taxes related to such premiums.

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(12) Includes reimbursed commuting costs for Dr. Hulme s travel from her residence to San Diego. Includes reasonable expenses for temporary housing, airfare, car service and other miscellaneous commuting expenses such as meals while Dr. Hulme is living in San Diego. All commuting reimbursement amounts are grossed up for applicable federal and state taxes. Also includes the value of company paid premiums for life, accidental death and dismemberment and long-term disability insurance in excess of Internal Revenue Service limits and a gross up payment for applicable federal and state taxes related to such premiums.

(13) Mr. Casdin was hired effective October 11, 2011. The salary and non-equity incentive plan payment above for 2011 reflect the prorated portion earned from Mr. Casdin s hire date through December 31, 2011. Mr. Casdin resigned as our Chief Financial Officer effective as of September 14, 2012.

(14) Mr. Casdin s 2011 stock option covering 9,615 shares was modified in connection with Mr. Casdin s Separation Agreement to partially accelerate the vesting of the option, as described below in the section below entitled Termination and Change of Control Benefits. The incremental fair value of this stock option, computed as of the modification date in accordance with ASC 718, is zero. Mr. Casdin s outstanding stock options covering 9,615 and 1,923 shares granted on October 11, 2011 terminated in 2012 in connection with his termination of employment.

(15) Includes $70,000, which represents severance pay and $6,115 for the continuation of medical benefits, each for three months in accordance with the Separation Agreement entered into in connection with Mr. Casdin s termination of employment, as described in detail in the section below entitled Termination and Change of Control Benefits. Also included as a component of other compensation is $3,776 of matching contributions was paid under the terms of our 401(k) plan, the value of company paid premiums of $835 for life, accidental death and dismemberment and long-term disability insurance in excess of Internal Revenue Service limits and $302 as a gross up payment for applicable federal and state taxes related to such premiums.

Annual Base Salary.

The compensation committee of the Board approved the following fiscal year base salaries for our named executive officers, which became effective on the later of January 1 of the applicable fiscal year or on their respective hire date (or with respect to Dr. Ekman, the date of his appointment as President).

Name	Fiscal 2011 Base Salary ($)	Fiscal 2012 Base Salary ($)
Randall E. Woods	$	$ 425,000
Lars Ekman, M.D., Ph.D.	$ 60,000	$ 60,000
Peter T. Slover	$	$ 235,000
Allison Hulme, Ph.D.	$ 330,000	$ 330,000
Alexander Casdin	$ 280,000	$ 280,000

Annual Performance-Based Bonus Opportunity.

In addition to base salaries, our named executive officers (other than Dr. Ekman) are eligible to receive an annual performance-based cash bonus, which is designed to provide an appropriate incentive to our executives to achieve defined annual corporate goals and to reward our executives for individual achievement towards these goals. Dr. Ekman was not eligible to participate in our performance-based bonus program for fiscal year 2012 or 2011. The annual performance-based bonus each executive officer is eligible to receive is based on the individual s target bonus, as a percentage of base salary. The amount of the performance-based bonus, if any, an executive earns is based on the achievement of certain corporate and individual performance goals recommended by the compensation committee and approved by the Board in the beginning of the year to which the bonus relates. There is no minimum or maximum bonus established for the named executive officers and, as a result, the bonus amounts vary from year to year based on corporate and individual performance. At the end of the year, the compensation committee recommends and our Board approves the extent to which the corporate and individual goals have been achieved, based on achievement of the corporate and individual goals and management s review and recommendation, except our executives do not make recommendations with respect to

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their own achievement. The Board may award a bonus in an amount above or below the target bonus, based on factors that the Board determines, with input from the compensation committee, are material to our corporate performance and provide appropriate incentives to our executives. Pursuant to their employment agreements or offer letters, each named executive officer has a target bonus represented as a percentage of base salary, or a target bonus percentage, each of which is set forth below.

Name	Target Bonus (%)
Randall E. Woods	40[(1)]
Lars Ekman, M.D., Ph.D.	N/A
Peter T. Slover	40
Allison Hulme, Ph.D.	50
Alexander Casdin	40

(1) In early 2013, the Board increased Mr. Woods target bonus percentage to 50%, effective beginning with Mr. Woods 2012 bonus.

The corporate and individual goals are determined by the Board based on the recommendation of the compensation committee and communicated to the named executive officers shortly following the beginning of each fiscal year. The corporate goals relate to our annual company goals and various business accomplishments which vary from time to time depending on our overall strategic objectives. The individual goals relate to each named executive officer s specific job responsibilities and often to the executive s performance towards reaching our corporate goals for the designated year. The proportional emphasis between corporate and individual goals does not necessarily involve a mathematical analysis or pre-established weighting of each goal. The Board may, but need not, establish a specific weighting amongst various corporate goals. The emphasis placed on goals may vary from time to time depending on our overall strategic objectives and the compensation committee s and Board s subjective determination of which goals have more impact on our performance.

For 2012, the corporate goals and relative overall weighting towards total corporate goal achievement were as follows:

Obtain the three month safety and efficacy data from the Transrectal Clinical Study (15%);

Initiate the first pivotal study for PRX302 for the treatment of the symptoms of BPH (20%);

Ensure that clinical material is available for the first pivotal study and complete the transfer of the manufacturing process from Dompé to BI (20%);

Obtain the draft reports for both the monkey repeat dose study and rat repro-toxicity study (5%);

Meet with and review our development plan for PRX302 for the treatment of the symptoms of BPH with various regulatory agencies (10%);

Obtain financing to allow for the initiation of the first pivotal study (10%);

Increase U.S. investor knowledge of the company through the attendance various investor healthcare conferences and one-on-one meetings with investors to increase share price (10%); and

Operate within 10% of the budget approved by the Board with respect to G&A (5%) and R&D (5%).

The individual goals for 2012 related generally to each named executive officer s overall contributions in his or her roles towards reaching our overall corporate goals. The Board did not assign a specific emphasis between corporate goals and individual goals. However, the Board established the following specific goals and relative weightings towards overall individual goal achievement for Mr. Casdin:

Establish a Finance Department which will meet the needs of the Company going forward (15%);

Obtain financing to allow for the initiation of the first pivotal study (40%);

Increase U.S. investor knowledge of the company through the attendance of various investor healthcare conferences and one-on-one meetings with investors to increase share price (15%);

Ensure compliance with applicable regulatory authorities (20%); and

Operate within 10% of the budget approved by the Board with respect to G&A (5%) and R&D (5%).

In early 2013, the compensation committee and our Board reviewed the 2012 corporate goals outlined above in detail, taking into consideration all circumstances, and determined that we achieved or partially achieved several of our corporate goals and missed other goals. The compensation committee and our Board also took into consideration certain events which occurred during the year which impacted our ability to meet certain goals outlined above including but not limited to the delay in the occurrence of certain regulatory meetings and the changes to our senior management team during 2012. The compensation committee recommended to the Board and the Board approved a 90% overall achievement of the 2012 corporate goals due to the following:

the receipt of the three month safety data from the Transrectal Clinical Study in the third quarter of 2012;

the significant progress in setting up the first pivotal study for PRX302 for the treatment of the symptoms of BPH with an expected initiation of the study in the second quarter of 2013 once we finalize the development plan for PRX302 after receipt of FDA guidance;

our completion of the transfer of the manufacturing process from Dompé to BI and the release of the clinical material for the start of the first pivotal study;

the receipt of the draft reports for both the monkey repeat dose study and rat repro-toxicity study;

we met with and reviewed our development plan for PRX302 for the treatment of the symptoms of BPH with a number of regulatory agencies during 2012 with final agreement on the development plan expected in the second quarter of 2013;

we delayed a financing which would allow for the initiation of the first pivotal study to allow for the finalization of the development plan for PRX302;

we attended four investor healthcare conferences during 2012 during which a number of one-on-one meetings were completed; while we feel that we dramatically increased the awareness of the U.S. investor of the Sophiris story we did not see an increase in our share price; and

taking into account certain items which were not contemplated by the 2012 budget but were approved by the Board during 2012, we operated within 10% of the budget approved by the Board with respect to G&A and R&D.

The compensation committee recommended to the Board and our Board determined not to consider individual goals, as each of our employee named executive officers (other than Mr. Casdin who was not eligible for a bonus) had contributed towards our corporate goal achievement. In addition, the Board determined that it was appropriate to increase Mr. Woods target bonus percentage to 50%, effective beginning with his bonus that relates to 2012. The Board authorized the payment of the 2012 bonuses to our named executive officers upon the completion of a successful financing or strategic transaction. At such time, each employee named executive officer who continues in our service will receive a bonus payment based on his or her target bonus percentage, multiplied by the executive s base salary and 90%, and prorated for the period of time the executive was employed in 2012. Such bonus amounts are $71,719, $62,745 and $148,500 for Messrs. Woods and Slover and Dr. Hulme, respectively. Because Mr. Casdin terminated service in September 2012, Mr. Casdin was not eligible for and will not receive a 2012 bonus payment.

Long-Term Incentive Compensation.

Our long-term, equity-based incentive awards are designed to align the interests of our named executive officers and our other employees, non-employee directors and consultants with the interests of our shareholders.

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Because vesting is based on continued service, our equity-based incentives also encourage the retention of our named executive officers through the vesting period of the awards.

We use stock options as the primary incentive vehicle for long-term compensation to our named executive officers because they are able to profit from stock options only if our stock price increases relative to the stock option s exercise price. We generally provide initial grants in connection with the commencement of employment of our named executive officers and from time to time as our Board, often through recommendation by our compensation committee, determines appropriate. We also provide annual retention grants at or shortly following the end of each year and performance-based grants when necessary to encourage our named executive officers to meet specific performance goals.

Prior to this offering, we have granted only stock options pursuant to our stock option plan, the terms of which are described below under Equity Compensation Plans and Other Benefit Plans Stock Option Plan. All options are granted with an exercise price no less than the fair market value of our common shares on the date of grant of each award.

The Board, often through recommendation by the compensation committee, determines the number of stock options to be awarded to our executive officers and directors. Stock options are awarded to our directors as described below under the section Non-Employee Director Compensation. Stock options are granted to reward individuals for current performance, expected future performance and value to the company. The size of awards made subsequent to the commencement of employment takes into account stock options already held by the individual. Other than awards to our Executive Chairman, stock options granted to our employees typically vest over a three-year period and may also vest subject to certain performance criteria.

In connection with the hiring of Mr. Woods, the Board granted a stock option to Mr. Woods for 94,496 shares. In connection with the hiring of Mr. Slover, the Board granted stock options to Mr. Slover for 4,807 and 961 shares. The option covering 961 shares granted to Mr. Slover vests upon the occurrence of the following performance goals as determined by our Board, subject to Mr. Slover s continued service with us through the achievement of such goals: complete a financing which will allow the company the ability to initiate its first pivotal study and ensure compliance with all regulatory authorities as it relates to the company s 2012 financial filings.

The vesting terms of the other 2012 stock options are described further in the footnotes to the Outstanding Equity Awards at Fiscal Year End table below. The option grants to Mr. Woods and Mr. Slover represented amounts the Board determined were appropriate for their level of responsibility and their prior work experience.

The Board did not award annual stock option retention grants to any of our named executive officers in 2012. The need to grant additional stock option grants in the form of annual retention grants will be reviewed by the compensation committee or Board on at least an annual basis.

In September, 2012 the performance goals for the stock options covering 1,923 and 3,846 shares granted to Dr. Ekman and Dr. Hulme, respectively, in 2011 were achieved and these options vested in full. In connection with his resignation from the company on September 14, 2012, the performance-based stock option covering 1,923 shares granted to Mr. Casdin in 2011 terminated, as the financing goals necessary for vesting in this option were not met as of the date of his resignation. In connection with Mr. Casdin s separation agreement, Mr. Casdin s time-based stock option covering 9,615 shares granted to Mr. Casdin in 2011 was accelerated to the extent of the portion of shares that would have vested had Mr. Casdin continued to provide services to us for the three-month period following his termination date, as described below further under the section Termination and Change of Control Benefits, and thereafter terminated.

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Perquisites, Health, Welfare and Retirement Benefits

Perquisites

In conjunction with the hiring of Dr. Hulme, we agreed to reimburse Dr. Hulme for regular travel costs from her residence to San Diego and for temporary housing in San Diego for a period of one year from her hire date. This reimbursement was extended for an additional year during September 2012. All amounts are grossed up for applicable federal and state taxes. In conjunction with the hiring of Mr. Woods, we agreed to pay to Mr. Woods an amount necessary to reimburse him for the cost of his medical insurance in lieu of Mr. Woods receiving such insurance under our employee benefit plans. This payment is grossed up for applicable federal and state taxes. A schedule of reimbursed expenses and the related tax gross-ups for Dr. Hulme and Mr. Woods are included in the footnotes to our Summary Compensation Table.

Other than what is outlined above, we do not provide perquisites or personal benefits to our named executive officers.

Health and Welfare Benefits

Our named executive officers, with the exception of Dr. Ekman, are eligible to participate in all of our employee benefit plans, including our medical, dental, vision, group life and disability insurance plans, in each case on the same basis as other employees.

We also pay the premiums for term life insurance, accidental death and dismemberment and long-term disability insurance for all of our employees, including our named executive officers with the exception of Dr. Ekman.

Retirement Benefits

In 2012, the Board authorized and directed management of the company to implement and maintain the Sophiris Bio Inc. 401(k) Plan, or the 401(k) Plan, a retirement savings defined contribution plan established in accordance with Section 401(a) of the U.S. Internal Revenue Code of 1986, as amended, or the Code, for the eligible employees of the company, including the current employee named executive officers. The 401(k) Plan was established effective as of January 1, 2012. Under this 401(k) Plan we provide safe harbor 401(k) matching contributions as discussed in the section below entitled Equity Compensation Plans and other Benefit Plans 401(k) Plan.

None of our named executive officers participate in or have account balances in qualified or non-qualified defined benefit plans, non-qualified defined contribution plans or pension plans sponsored by us.

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Outstanding Equity Awards at Fiscal Year End

The following table sets forth specified information concerning unexercised stock options and equity incentive plan awards for each of the named executive officers outstanding as of December 31, 2012.

	Option Awards[1]					
		Number of Securities Underlying Unexercised Options				
Name	Grant Date	(#) Exercisable	(#) Unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option Exercise Price ($)[2]	Option Expiration Date
Randall E. Woods	10/04/2012		94,496[4]		15.60	10/03/2017
Lars Ekman, M.D., Ph.D.	02/16/2011	1,730			35.88	02/15/2016
	06/09/2011	9,615			30.68	06/08/2016
	06/09/2011	1,923			30.68	06/08/2016
Peter Slover	04/04/2012		4,807[4]		24.96	04/03/2017
	04/04/2012			961[3]	24.96	04/03/2017
Allison Hulme, Ph.D.	06/09/2011	6,410	12,820[5]		30.68	06/08/2016
	06/09/2011	3,846			30.68	06/08/2016
Alexander Casdin[6]						

(1) All of the options were granted under our stock option plan, the terms of which are described below under Equity Compensation Plans and Other Benefit Plans Stock Option Plan.

(2) The Canadian dollar-denominated exercise price has been converted to U.S. dollars using a U.S. dollar per Canadian dollar exchange rate of 1.0051, which was the year end rate as of December 31, 2012.

(3) The vesting conditions for these performance based options are described above under Long-term Incentive Compensation.

(4) 33% of the shares subject to the option vest and become exercisable from the date of employment with the remaining shares subject to the option vesting in equal annual installments over the next two years such that all shares subject to the options will be fully vested three years from the date of employment.

(5) 33% of the shares subject to the option vest and become exercisable one year from the date of grant with the remaining shares subject to the option vesting in equal annual installments over the next two years such that all shares subject to the options will be fully vested on June 9, 2014.

(6) Upon Mr. Casdin s resignation from the company on September 14, 2012, options covering 1,923 shares were forfeited as the vesting conditions were not completed prior to such date. In connection with Mr. Casdin s separation agreement, Mr. Casdin s time-based stock option covering 9,615 shares granted to Mr. Casdin in 2011 was accelerated and terminated prior to December 31, 2012, as described below further under the section Termination and Change of Control Benefits.

Employment Agreements with Executive Officers

We entered into an employment agreement with Mr. Woods on August 16, 2012, in connection with his commencement of employment as our Chief Executive Officer and President. Pursuant to the employment agreement, Mr. Woods is entitled to an annual base salary of $425,000 (as Mr. Woods was hired on August 16, 2012, he earned $159,375 of his annual salary during 2012), a discretionary performance bonus of 40% of Mr. Woods annual base salary, pro rated for his partial year of service in 2012. Additionally, Mr. Woods employment agreement provided for a stock option grant and certain severance benefits upon a termination by us without cause and termination without cause or resignation for good reason in connection with a change of control of the company. The employment agreement also provides that Mr. Woods is subject to certain

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confidentiality and non-competition restrictions during and following the term of his employment with us and is further described in detail in the section below entitled Termination and Change of Control Benefits.

Dr. Ekman does not have an agreement covering his services to us. However, in accordance with our non-employee director compensation program, Dr. Ekman received an annual cash retainer of $45,000 and a stock option grant for 1,730 shares in 2011 for his service as our Executive Chairman. In connection with his appointment as our Executive Chairman and President in April 2011, the Board committed to increase Dr. Ekman s annual compensation to $60,000 and granted him stock options covering a total of 11,538 shares.

We entered into an employment agreement with Mr. Slover on March 19, 2012, in connection with his commencement of employment as our Head of Finance and Principal Accounting Officer. Pursuant to the employment agreement, Mr. Slover is entitled to an annual base salary of $235,000 (as Mr. Slover was hired on April 4, 2012, he earned $174,292 of his annual salary during 2012), a discretionary performance bonus of 40% of Mr. Slover s annual base salary, pro rated for his partial year of service in 2012. Additionally, Mr. Slover s employment agreement provided for stock option grants and that Mr. Slover is subject to certain confidentiality and non-competition restrictions during the term of his employment with us.

Pursuant to employment agreements with us, Mr. Casdin was entitled to an annual salary of $280,000 and Dr. Allison Hulme was entitled to an annual salary of $330,000. Both Mr. Casdin and Dr. Hulme were entitled to additional benefits, including the stock option grants each received in 2011 and the opportunity to earn a performance based bonus based on a target bonus percentage specified in their agreements, if certain performance goals are achieved. The agreements with both Mr. Casdin and Dr. Hulme provide that each is subject to certain confidentiality and non-competition restrictions during and following the term of their respective employment with the company. Mr. Casdin entered into a Separation Agreement with us in connection with his termination of employment in October 2012, as described in detail in the section below entitled Termination and Change of Control Benefits.

Compensation Recovery Policies

The Board and the compensation committee have not determined whether they would attempt to recover bonuses from our executive officers if the performance objectives that led to the bonus determination were to be restated, or found not to have been met to the extent originally believed by the compensation committee. However, as a public company subject to the provisions of Section 304 of the Sarbanes-Oxley Act of 2002, if we will be required as a result of misconduct to restate our financial results due to our material noncompliance with any financial reporting requirements under the federal securities laws, our president and chief financial officer may be legally required to reimburse us for any bonus or other incentive-based or equity-based compensation they receive. In addition, we will comply with the requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act and will adopt a compensation recovery policy once final regulations on the subject have been adopted.

Equity Compensation Plans and Other Benefit Plans

Stock Option Plan

Our Amended and Restated 2011 Stock Option Plan, or the Plan, was last approved by our shareholders on June 6, 2012. The purpose of the Plan is to provide a share-related mechanism to attract, retain and motivate qualified executives (including directors), employees and consultants of the company, each referred to herein as a Participant, to incent such individuals to contribute toward the long-term goals of the company, and to encourage such individuals to acquire shares of the company as long-term investments. The Plan is administered by a committee which shall, from time to time and in its sole discretion, determine those executives, employees and consultants of the company, if any, to whom options are to be granted. Presently, such committee is

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comprised of the members of the compensation committee, who make recommendations to the full Board with respect to grants of options.

Subject to certain adjustments, the number of common shares which will be available for purchase pursuant to options granted under the Plan is 10% of the number of issued and outstanding common shares (on a non-diluted basis) on the particular grant date, or the Outstanding Issue. If any option expires or otherwise terminates for any reason without having been exercised in full, the number of shares in respect of such expired or terminated option shall again be available for the purposes of granting options pursuant to the Plan. The maximum number of options which may be granted to any one Participant under the Plan within any 12-month period is 5% of the Outstanding Issue.

As of December 31, 2012, a total of 240,986 options have been granted and remain outstanding under the Plan (representing approximately 7.7% of the issued and outstanding common shares on a non-diluted basis) and a total of 74,000 options remain available for grant under the Plan (representing approximately 2.3% of the issued and outstanding common shares on a non-diluted basis).

The exercise price at which a Participant may purchase a common share upon the exercise of an option is the Market Value of such shares as of the grant date. The Market Value of the shares for a particular grant date is the closing trading price of the shares on the primary organized trading facility, as determined by the committee, on which the shares are listed on the trading day immediately preceding the grant date, subject to any adjustments as may be required to secure all necessary regulatory approvals; provided that if the shares are not listed on any organized trading facility, then the Market Value will be, subject to any adjustments as may be required to secure all necessary regulatory approvals, such value as is determined by the committee to be the fair value of the shares, taking into consideration all factors that the committee deems appropriate, including, without limitation, recent sale and offer prices of the shares in private transactions negotiated at arms length.

The vesting schedule for an option, if any, shall be determined by the committee. Notwithstanding the foregoing, the committee may elect, at any time, to accelerate the vesting schedule of one or more options in the event of certain triggering events set out in the Plan. Additionally, in the event of a change of control of the company, the options outstanding shall become immediately exercisable on such date the change of control has been deemed to have occurred. The Plan generally defines a change in control as the occurrence of either: (1) a person or entity, or a group thereof acting in concert, directly or indirectly acquires beneficial ownership of more than 50% of our then outstanding shares (on a non-diluted basis); or (2) a majority of the directors elected at any annual or extraordinary general meeting of shareholders of the company are not individuals nominated by our then-incumbent Board.

The expiration date of an option granted under the Plan shall be no later than the 10th anniversary of the grant date of such option, except where an option expires during an black-out period in which case it will expire 10 business days after the black-out period is lifted and the company notifies the Participant of the extension of the expiration date. In the event that a Participant holds his or her option as a director or officer of the company and such Participant ceases to hold such position other than by reason of death or disability, the expiration date of the option shall be, unless otherwise expressly provided for in the option certificate, the 90th day following the date the Participant ceases to hold such position unless the Participant ceases to hold such position as a result of: (i) ceasing to meet the qualifications set forth in the corporate legislation applicable to the company; (ii) a special resolution having been passed by the shareholders of the company removing the Participant as a director of the company; or (iii) an order made by any regulatory authority having jurisdiction to so order, in which case the expiration date shall be the date the Participant ceases to hold such position.

In the event that a Participant holds his or her option as an employee or consultant of the company and such Participant ceases to hold such position other than by reason of death or disability, the expiration date of the option shall be, unless otherwise expressly provided for in the option certificate, the 90th day following the date

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the Participant ceases to hold such position, unless the Participant ceases to hold such position as a result of: (i) termination for cause; or (ii) an order made by any regulatory authority having jurisdiction to so order, in which case the expiration date shall be the date the Participant ceases to hold such position. If the Participant ceases to hold such position as a result of resigning or terminating his or her position, the expiration date shall be the 30th day following the date the Participant ceases to hold such position.

Subject to certain limited circumstances, options granted under the Plan are non-assignable and non-transferable.

Subject to the requisite shareholder and regulatory approvals set forth below, the committee may from time to time amend or revise an existing option or the Plan or the terms and conditions of any option thereafter to be granted provided however that no such amendment or revision may, without the consent of the Participant, (i) materially decrease the rights or benefits accruing to a Participant or (ii) materially increase the obligations of a Participant.

The committee may, subject to receipt of requisite shareholder and regulatory approval, make the following amendments to the Plan:

(i) any amendment to the number of securities issuable under the Plan, including an increase to a fixed maximum number of securities or a change from a fixed maximum number of securities to a fixed maximum percentage. A change to a fixed maximum percentage which was previously approved by shareholders will not require additional shareholder approval;

(ii) the addition of any form of financial assistance or any amendment to a financial assistance provision which is more favourable to participants under the Plan;

(iii) a discontinuance of the Plan; and

(iv) any other amendments that may lead to significant or unreasonable dilution in our outstanding securities or may provide additional benefits to eligible participants under this Plan, especially insiders of the company, at the expense of the company and our existing shareholders.

The committee may without shareholder approval, subject to receipt of regulatory approval, where required, in its sole discretion make all other amendments to the Plan or any option that are not of the type contemplated above including, without limitation:

(i) amendments of a housekeeping nature including, but not limited to, of a clerical, grammatical or typographical nature;

(ii) correct any defect, supply any information or reconcile any inconsistency in the Plan in such manner and to such extent as shall be deemed necessary or advisable to carry out the purposes of the Plan;

(iii) a change to the vesting provisions of any option or the Plan;

(iv) amendments to reflect any requirements of any regulatory authorities to which we are subject, including the TSX;

(v) a change to the termination provisions of an option which does not result in an extension beyond the original expiration date of such option;

(vi) amendments to the definition of change of control;

(vii) the addition of a cashless exercise feature, payable in cash or securities;

(viii) a change to the class of participants that may participate under the Plan; and

(ix) amendments to reflect changes to applicable laws or regulations.

Notwithstanding the foregoing, the company shall additionally obtain requisite shareholder approval in respect of amendments to the Plan or any option that are contemplated immediately above to the extent such

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approval is required by any applicable regulatory rules. Furthermore, if the exercise price of an option held by a Participant who is an insider of the company is reduced or if the term of an option held by a Participant who is an insider of the company is extended, the insider must not exercise the option at the reduced exercise price or with the extended term, as the case may be, until the reduction in exercise price or extension of the term has been approved by the disinterested shareholders of the company.

Equity Compensation Plan Information

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2012:

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)[1]	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[2]:	240,986	$ 23.92	74,000
Equity compensation plans not approved by security holders:	None	N/A	N/A
Total	240,986	$ 23.92	74,000

(1) The Canadian dollar-denominated exercise price has been converted to U.S. dollars using a U.S. dollar per Canadian dollar exchange rate of 1.0051, which was the year end rate as of December 31, 2012.

(2) Represents our common shares issuable pursuant to our stock option plan, the material terms of which are described above under Equity Compensation Plans and Other Benefit Plans Stock Option Plan.

401(k) Plan

All of our full-time employees are eligible to participate in our 401(k) Plan, which is a retirement savings defined contribution plan established in accordance with Section 401(a) of the Code. Pursuant to our 401(k) Plan, employees may elect to defer their eligible compensation into the plan on a pre-tax basis, up to the statutorily prescribed annual limit of $17,000 in 2012 (additional salary deferrals not to exceed $5,500 are available to those employees 50 years of age or older) and to have the amount of this reduction contributed to our 401(k) Plan. We provide a $1.00 match for every dollar our employees elect to defer up to 3% of their eligible compensation and a $0.50 match for every dollar our employees elect to defer in excess of 3% and up to 5% of their eligible compensation. In general, eligible compensation for purposes of the 401(k) plan includes an employee s wages, salaries, fees for professional services and other amounts received for personal services actually rendered in the course of employment with us, to the extent the amounts are included in gross income, and subject to certain adjustments and exclusions required under the Code. The 401(k) Plan currently does not offer the ability to invest in our securities.

Termination and Change of Control Benefits

Pursuant to our Plan, all outstanding unvested stock options of our NEOs shall become immediately exercisable on the date of a change of control, as further described in the section above entitled Equity Compensation Plans and other Benefit Plans Stock Option Plan .

The employment agreement we entered into with Mr. Woods in 2012 provides that upon a termination by us without cause (and other than due to Mr. Woods death or disability), Mr. Woods will be entitled to (1) continued

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base salary for a severance period equal to 6 months (in the event such termination occurs within the one year period following Mr. Woods commencement of employment with us) or 12 months (in the event such termination occurs following the one year anniversary of Mr. Woods hire date) and (2) continued payment of health insurance benefits for up to the severance period described in (1) above. The base salary payments may be accelerated and paid in a lump sum if such payments would be subject to Section 409A of the Code. Additionally, in the event that Mr. Woods is terminated by us without cause (and other than due to Mr. Woods death or disability) or Mr. Woods resigns for good reason (including Mr. Woods resignation due to a relocation of his principle place of employment or material reduction of his base salary) within the one month period preceding or the twelve month period following a change of control (as defined in the Plan), all of Mr. Woods unvested stock options and other compensatory stock awards will become immediately vested and exercisable in full. The severance benefits provided under Mr. Woods employment agreement require that Mr. Woods agree to a release of claims against the company.

We entered into a separation agreement with Mr. Casdin in connection with his resignation of employment with us on September 14, 2012. Pursuant to the separation agreement, Mr. Casdin agreed to a release of claims against the company and received (1) continued base salary for three months; (2) three months of health insurance payments and (3) acceleration of the portion of shares underlying Mr. Casdin s 2011 time-based stock option that would have vested had he continued to provide services to us for the three-month period following his termination date. In accordance with the Plan, all of Mr. Casdin s outstanding stock options terminated in connection with his termination of employment.

Non-Employee Director Compensation

Pursuant to our non-employee director compensation program, we compensate non-employee members of our Board for their services in the form of cash retainers and option grants under our Plan. In 2012, we provided annual cash retainers of $30,000 to each of our non-employee members of the Board. The Chairman of the Board was entitled to receive an additional $15,000 cash retainer and the Chairman of the audit committee and the Chairman of the compensation committee received an additional $7,000 and $3,000 cash retainer, respectively. The director fees were paid quarterly, in arrears, as per the terms of the non-employee director s compensation program.

The Board, after recommendation by the compensation committee, may determine to grant each non-employee director an option award from time to time. In 2012, the Board granted Mr. Knauf an option award for 1,154 shares in connection with is appointment to the Board. Stock options granted to our non-employee directors are granted under and subject to the terms of our Plan, as further described in the section above entitled Equity Compensation Plans and other Benefit Plans Stock Option Plan and generally vest over a one year period.

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the year ended December 31, 2012 to each of our non-employee directors:

Director Compensation

The following table discloses all compensation provided to the non-employee directors for the most recently completed financial year ending December 31, 2012:

Name[1]	Fees earned or paid in cash ($)[5]	Option awards ($)[6]	Total ($)
John (Jack) Geltosky, Ph.D.	30,000		30,000
Jim Heppell	29,769		41,946
Frank Holler[2]	3,793		3,793
Noah Knauf[4]	2,500	8,226	10,726
Jonathan Leff[3]	27,500		27,500
William R. Rohn	37,000		37,000
Amit Sobti[7]	33,000		33,000
Nishan de Silva, Ph.D.[2]	3,770		3,770

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Notes:

(1) Dr. Ekman is also a non-employee director of the company. As an NEO, Dr. Ekman s compensation is disclosed in the Summary Compensation Table above.
(2) Mr. Holler and Dr. de Silva resigned as directors in February 2012.
(3) Mr. Leff resigned as a director in November 2012.
(4) Mr. Knauf was appointed to as a director in November 2012. Mr. Knauf resigned as a director on July 8, 2013.
(5) All of Mr. Heppell s and Mr. Holler s fees are paid in Canadian dollars. All Canadian dollar payments have been converted to U.S. dollars for purposes of this table using a quarterly U.S. dollar per Canadian dollar exchange rate for the first, second, third and fourth calendar year quarters of 2012 of 1.0061, 0.9727, 1.0171 and 1.0051, respectively.
(6) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during 2012 computed in accordance with ASC 718 and excluding the effect of estimated forfeitures. Assumptions used in the calculation were as follows: dividend rate 0%, risk-free interest rate 1.2%, expected life of the option term (years) 4.0, volatility 67.4% and forfeiture rate 8.6%. The exercise price for stock option awards were denominated in Canadian dollars on the date of the grant. The amounts reflected in this column were converted to U.S. dollars using the U.S. dollar per Canadian dollar exchange rate of 0.9936, which was the exchange rate on the November 30, 2012 date of grant. All outstanding option-based awards for the non-employee directors of the company as of December 31, 2012 are set out in the following table:
(7) Mr. Sobti resigned as a director on July 8, 2013.

All outstanding option-based awards for the non-employee directors of the company as of December 31, 2012 are set out in the following table:

	Option Awards [1]				
		Number of Securities Underlying Unexercised Options			
Name	Grant Date	(#) Exercisable	(#) Unexercisable	Option Exercise Price ($)[3]	Option Expiration Date
John Geltosky, Ph.D.	09/29/2008	961		$ 31.20	09/28/2013
	09/03/2009	480		26.00	09/3/2014
	02/16/2011	576		35.88	02/16/2016
Jim Heppell	09/03/2009	1,826		26.00	09/03/2014
	02/16/2011	576		35.88	02/16/2016
Noah Knauf[4]	11/30/2012		1,153[2]	14.04	11/29/2017
Jonathan Leff	02/16/2011	1,153		35.88	02/28/2013
Bill Rohn	02/16/2011	1,153		35.88	02/16/2016
Amit Sobti[4]	02/16/2011	1,153		35.88	02/16/2016

(1) All of the options were granted under our stock option plan, the terms of which are described below under Equity Compensation Plans and Other Benefit Plans Stock Option Plan.
(2) 25% of the shares subject to the option vest and become exercisable three months from the date of grant with the remaining shares subject to the option vesting in equal quarterly installments over the next nine months such that all shares subject to the options will be fully one year from the grant date.
(3) The Canadian dollar-denominated exercise price has been converted to U.S. dollars using a U.S. dollar per Canadian dollar exchange rate of 1.0051, which was the year end rate as of December 31, 2012.
(4) Messrs. Knauf and Sobti resigned as directors on July 8, 2013.

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CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2010 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

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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 March 2010, we completed a brokered private placement financing, or the 2010 Financing. The 2010 Financing resulted in the issuance of 217,027 units at a price of CND$23.40 per unit, or $22.88 per unit, applying the conversion rate as of the date of issuance, with each unit consisting of one of our common shares and 0.5 of a common share purchase warrant. BC Advantage Funds (VCC) Ltd., one of our principal shareholders, purchased 42,735 units in the 2010 Financing. Each common share purchase warrant entitles the holder to purchase one of our common shares at a price of CND$33.80, or $33.28 per common share, applying the conversion rate as of the date of issuance, exercisable for a period of five years from the date of issue.

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 of the 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, the 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 the 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. The Investment Agreement was terminated in July 2013.

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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 Employment Agreements with Executive Officers under Executive and Director Compensation.

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.

Participation in Offering

Certain of our existing shareholders and their affiliated entities have agreed to purchase approximately $22.4 million of our common shares in this offering at the public offering price.

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

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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

Prior to the closing of this offering, we plan to adopt a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our common stock, 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 stock, 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 any 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.

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PRINCIPAL SHAREHOLDERS

The following table sets forth information regarding beneficial ownership of our share capital as of July 10, 2013 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common shares;
- each of our directors;
- each of our named executive officers; and
- all of our directors and current executive officers as a group.

The percentage ownership information under the column entitled Before offering is based on 3,149,869 common shares outstanding as of July 10, 2013, which reflects the 52-for-1 share consolidation of our common shares. The percentage ownership information under the column entitled After offering is based on the sale of 13,000,000 common shares in this offering.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common shares. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include common shares issuable pursuant to the exercise of options or warrants that are either immediately exercisable or exercisable on or before September 8, 2013, which is 60 days after July 10, 2013. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Certain of our existing shareholders and their affiliated entities have agreed to purchase approximately $22.4 million of our common shares in this offering at the public offering price. The following table reflects the purchase by Tavistock of $8.0 million of our common shares in this offering.

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

Name and address of beneficial owner	Number of shares beneficially owned	Percentage of shares beneficially owned Before offering	After offering
5% or greater shareholders			
Tavistock Life Sciences Co.[1] 440 Stevens Ave, Suite 100 Solana Beach, CA 92075	961,538	30.5%	15.9%
Warburg Pincus Private Equity X, L.P.[2]. 450 Lexington Avenue New York, NY 10017	1,089,744	27.8%	6.4%
BC Advantage Funds (VCC) Ltd.[3] 410-221 West Esplanade	209,928	6.6%	1.3%

North Vancouver, BC V7M 3J3

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Name and address of beneficial owner	Number of shares beneficially owned	Percentage of shares beneficially owned Before offering	After offering
Directors and named executive officers			
Randall E. Woods[4]	31,499	1.0%	*
Alexander Casdin[5]	0	*	*
Allison Hulme[6]	16,667	*	*
Peter T. Slover[7]	1,603	*	*
Lars Ekman[8].	23,452	*	*
John Geltosky[9]	2,019	*	*
Jim Heppell[10]	245,686	7.7%	1.5%
William Rohn[11]	5,000	*	*
All current executive officers and directors as a group (seven persons)[12]	325,926	10.1%	2.0%

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

(1) Consists of 865,385 shares of common stock that are beneficially owned by Boxer Capital, LLC (Boxer Capital) and 96,154 shares of common stock that are beneficially owned by MVA Investors, LLC (MVA). Boxer Asset Management is the managing member and majority owner of Boxer Capital. Joseph Lewis is the sole indirect owner and controls Boxer Management. MVA is the independent, personal investment vehicle of certain employees of Boxer Capital and Tavistock Life Sciences Company, which is a Delaware corporation and an affiliate of Boxer Capital. The principal business address of Boxer Capital, and MVA is: 440 Stevens Avenue, Suite 100, Solana Beach, CA 92075. The principal business address of both Boxer Asset Management and Joseph Lewis is: c/o Cay House P.O. Box N-7776 E.P. Taylor Drive Lyford Cay, New Providence, Bahamas.

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

(3) Includes 188,560 shares and 21,368 common share purchase warrants that are immediately exercisable by B.C. Advantage Funds (VCC) Ltd. B.C. Advantage Funds (VCC) Ltd. is a widely-held investment fund. These securities have been pledged as security.

(4) Includes 31,499 shares subject to options exercisable within 60 days of July 10, 2013.

(5) Effective as of September 14, 2012, Mr. Casdin resigned as our Chief Financial Officer.

(6) Includes 16,667 shares subject to options exercisable within 60 days of July 10, 2013.

(7) Includes 1,603 shares subject to options exercisable within 60 days of July 10, 2013.

(8) Includes 10,183 shares and 13,269 shares subject to options exercisable within 60 days of July 10, 2013.

(9) Includes 2,019 shares subject to options exercisable within 60 days of July 10, 2013.

(10) Includes 11,150 shares and 2,404 shares subject to options exercisable within 60 days of July 10, 2013. Also includes 188,560 shares and 21,368 common share purchase warrants beneficially owned by B.C. Advantage Funds (VCC) Ltd., 19,231 shares owned by Lions Liquidity Investment Fund I Limited Partnership and 630 shares and 2,344 common share purchase warrants owned by Lions Capital Corp., for which Mr. Heppell may be deemed to share voting and investment control. Mr. Heppell disclaims ownership of such shares held by B.C. Advantage Funds (VCC) Ltd., Lions Liquidity Investment Fund I Limited Partnership and Lions Capital Corp., except to the extent of his pecuniary interest therein, if any.

(11) Includes 3,846 shares and 1,154 shares subject to options exercisable within 60 days of July 10, 2013.

(12) Includes the shares and shares subject to options exercisable within 60 days of July 10, 2013 referred to in footnotes (4), (6), (7), (8), (9), (10) and (11).

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DESCRIPTION OF SHARE CAPITAL

Upon closing of this offering, our authorized capital shares will consist 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 June 30, 2013, our outstanding common shares were held by 31 shareholders of record.

As of June 30, 2013, approximately 41.1% of our outstanding common shares were held by 10 shareholders of record in the United States.

Upon closing of this offering, based upon 3,149,869 shares outstanding as of June 30, 2013, our authorized share capital will consist of an unlimited number of common shares, each without par value of which 16,149,869 will be issued and outstanding, and an unlimited number of preferred shares, issuable in series, each without par value, none of which will be issued and outstanding.

Market Information

Our common shares are traded on the Toronto Stock Exchange, or TSX, under the symbol SHS. The following table sets forth the high and low sales prices for our common stock for the periods indicated, as reported on the TSX. The closing price of our common shares on the TSX as of August 14, 2013 is $8.32 per share which reflects the 52-for-1 share consolidation of our common shares. We have converted these amounts to U.S. dollars using the exchange rate on the date of the of corresponding high or low sales price.

2010	**CND$ High**	**US$ High**	**CND$ Low**	**US$ Low**
First Quarter	$ 51.48	$ 49.40	$ 21.32	$ 20.28
Second Quarter	32.76	32.24	20.80	19.76
Third Quarter	23.40	22.88	18.72	18.20
Fourth Quarter	37.96	37.44	18.72	18.72
2011	**High**	**High**	**Low**	**Low**
First Quarter	$ 37.96	$ 37.96	$ 24.96	$ 25.48
Second Quarter	38.48	40.56	26.52	27.56
Third Quarter	28.08	29.64	18.20	17.68
Fourth Quarter	20.28	19.24	15.08	14.56
2012	**High**	**High**	**Low**	**Low**
First Quarter	$ 21.32	$ 21.32	$ 15.60	$ 15.60
Second Quarter	24.96	24.96	16.64	16.12
Third Quarter	20.80	20.80	15.60	16.12
Fourth Quarter	16.64	17.16	11.96	11.96
2013	**High**	**High**	**Low**	**Low**
First Quarter	$ 14.56	$ 14.04	$ 8.84	$ 8.84
Second Quarter	$ 18.20	$ 17.68	$ 11.44	$ 10.92

Share Capital

Our authorized share capital consists of an unlimited number of common shares without par value and an unlimited number of preferred shares, issuable in one or more series, without par value.

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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, and the common shares to be issued in this offering will be, duly authorized, validly issued, fully paid and nonassessable.

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 June 30, 2013, there were 918,868 common share purchase warrants outstanding, which expire between March 2015 and July 2018. Each of these warrants entitles the holder to purchase one common share at prices ranging between CND$26.00, or $24.72, as converted, and CND$33.80, or $32.14, as converted, 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.

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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. In connection with the current offering, each shareholder that has registration rights has agreed not to sell or otherwise dispose of any securities without the prior written consent of the representatives of underwriters for a period of 180 days after the date of this prospectus, subject to certain terms and conditions. For more information regarding such terms and conditions, see Shares Eligible for Future Sale Lock-Up Agreements and Underwriting.

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. We expect that we will obtain from Warburg Pincus a waiver of any and all rights to have its registrable securities included in this offering.

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.

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 300,590 common shares have been granted and are outstanding as of June 30, 2013 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

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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 and on the Toronto Stock Exchange

We have applied to have our common shares approved for listing on the NASDAQ Global Market under the symbol SPHS. Our common shares currently trade on the Toronto Stock Exchange under the symbol SHS.

Transfer Agent and Registrar

Upon the closing of this offering, the transfer agent and registrar for our common shares in the United States and Canada will be Computershare Investor Services Inc.

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MATERIAL DIFFERENCES BETWEEN THE BCBCA AND THE DGCL

Our corporate affairs are governed by our articles of association and the provisions of applicable laws of British Columbia, including the British Columbia Business Corporations Act, or the BCBCA. The BCBCA differs from the various state laws applicable to U.S. corporations and their shareholders. The following table provides a summary of the material differences between the provisions of the BCBCA and the Delaware General Corporation Law, or the DGCL.

Authorized Share Capital

As permitted by the BCBCA and our articles, our authorized share capital consists of (i) an unlimited number of common shares without par value, with special rights and restrictions attached and (ii) an unlimited number of preferred shares without par value, with special rights and restrictions attached.

Under our articles, the directors have the authority to issue preferred shares in one or more series, with such designations and special rights and restrictions as the directors may determine.

Under the DGCL, a corporation s certificate of incorporation must specify the number of shares of each class of stock and their par value, or include a statement that such shares are without par value. The certificate of incorporation must also set forth the designations, powers, preferences, rights, qualifications, limitations and restrictions of each class of shares, if any. Under the DGCL, a corporation s certificate of incorporation give the board of directors the authority to issue preferred stock in one or more series, with such designations and special rights and restrictions as determined by the board of directors.

Dividends

Under the BCBCA and our articles, dividends may be declared at the discretion of the board of directors. Any dividends declared shall be subject to the rights, if any, of shareholders holding shares with special rights as to dividends. Our directors may declare dividends unless there are reasonable grounds for believing that Sophiris is insolvent or the payment of such dividends would render Sophiris insolvent.

The DGCL generally provides that, subject to certain restrictions, the directors of a corporation may declare and pay dividends upon the shares of its capital stock either out of the corporation s surplus or, if there is no such surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year. Further, the holders of preferred or special stock of any class or series may be entitled to receive dividends at such rates, on such conditions and at such times as stated in the certificate of incorporation.

Shareholder Action by Written Consent

Under the BCBCA and our articles, shareholder action without a meeting may be taken by written resolution signed by all of the shareholders who would be entitled to vote on the relevant issue at a general meeting.

Under the DGCL, any action required or permitted to be taken at a stockholder meeting may be taken without a meeting if consents in writing are signed by the holders of outstanding stock having at least the minimum number of votes necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted, unless otherwise provided in the certificate of incorporation.

Typically, public company certificates of incorporation prohibit actions by written consent of the stockholders.

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Election of Directors

Neither our articles nor the BCBCA provide for cumulative voting.

Under the DGCL, stockholders are not entitled to cumulative voting in the election of directors unless provided for in the corporation s certificate of incorporation.

Removal of Directors

As permitted under the BCBCA, our articles provide that a director may be removed before the expiration of their term by a special resolution of shareholders. Our articles also provide that the directors may remove any director before the expiration of their term if the director is convicted of an indictable offence or if the director ceases to be qualified to act as a director.

Under the DGCL any director may be removed, with or without cause, by the affirmative vote of a majority of the shares then entitled to vote at an election of directors, unless the board is classified, cumulative voting is permitted by the certificate of incorporation or the certificate of incorporation provides otherwise.

Required Vote for Certain Transactions

Under the BCBCA, certain extraordinary corporate actions, such as continuances, certain amalgamations, sales, leases or other dispositions of all, or substantially all of, the property of a corporation (other than in the ordinary course of business), liquidations, dissolutions and certain arrangements, are required to be approved by special resolution of shareholders.

Under the DGCL, certain mergers, consolidation, sale, lease, exchange or other disposition of all, or substantially all, the property and assets of a corporation or dissolution of the corporation requires the approval of a majority of the outstanding voting stock of the corporation entitled to vote thereon.

Amendment of Organizing Documents

As permitted by the BCBCA, under our articles, any amendment to the notice of articles or articles generally requires approval by an ordinary or special resolution of the shareholders. In the event that an amendment to the articles would prejudice or interfere with a right or special right attached to issued shares of a class or series of shares, such amendment must be approved separately by the holders of the class or series of shares being affected.

The DGCL provides that a corporation may amend its certificate of incorporation if its board of directors has adopted such amendment, followed by the affirmative vote of a majority of the outstanding voting stock and a majority of the outstanding shares of each class entitled to vote on the amendment as a class. In the event the amendment would alter the aggregate number of authorized shares of a class of stock, their par value, or the powers, preferences or special rights of the shares of a class so as to affect them adversely, the holders of the outstanding shares of the class are entitled to vote as a class upon a proposed amendment, whether or not entitled to vote thereon by the certificate of incorporation.

Quorum of Shareholders

As permitted under the BCBCA, our articles provide that a quorum for general meetings of shareholders is two persons present and being, or representing by proxy, shareholders holding in the aggregate not less than 5% of the issued shares entitled to be voted at the meeting.

Under the DGCL, unless otherwise provided in the certificate of incorporation, with respect to any matter, a quorum for a meeting of stockholders requires the holders of a majority of the shares entitled to vote are represented at the meeting in person or by proxy.

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Shareholder Access to Corporate Records

Under the BCBCA, specified books and records of the corporation must be available for inspection by any of our shareholders at the registered and records office.

Under the DGCL, a stockholder of record has the right to inspect the books and records of the corporation, provided that such inspection is for a proper purpose which is reasonably related to such stockholder s interest as a stockholder.

Annual Meetings of Shareholders

Our articles provide that an annual general meeting must be held at least once in each calendar year, and not more than 15 months after the last annual reference date, at such time and place as may be determined by the directors. An annual meeting of shareholders may be held at a location outside British Columbia if the location for the meeting is approved by a directors resolution. Sophiris must provide notice of the annual general meeting to each shareholder entitled to attend the meeting, to each director and to the auditor of the company at least 21 days before the meeting date.

Under the DGCL, a corporation must hold an annual meeting of stockholders in a place designated by the certificate of incorporation or bylaws, whether inside or outside of Delaware, or, if not so designated, as determined by the board of directors and on a date and at a time designated in the bylaws, except as otherwise provided by law. Written notice of every meeting of stockholders must be given to each stockholder of record not less than 10 nor more than 60 days before the date of the meeting.

Special Meetings of Shareholders

Under our articles, the directors have the power at any time to call a meeting of the shareholders. Under the BCBCA, the holders of not less than 5% of the issued shares of a corporation that carry the right to vote at a general meeting may requisition the directors to call a meeting of shareholders.

Under the DGCL, special meetings of stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or the bylaws. Typically public company certificates of incorporation do not authorize shareholders to call special meetings.

Anti-takeover Provisions and Interested Shareholder Transactions

As permitted by the BCBCA, our articles provide that our board of directors may fix the number of preferred shares in, and determine the designation of the shares of, each series and create, define and attach rights and restrictions to the preferred shares without shareholder approval. Neither the BCBCA nor our articles restrict us from adopting a shareholder rights plan. The BCBCA does not restrict related party transactions. However, in Canada takeovers and other related party transactions are addressed in provincial securities legislation and policies which may apply to us.

Under the DGCL, a certificate of incorporation may provide the board of directors with the ability to designate the terms of and issue a new class or series of preferred stock, and to issue a stockholder rights plan. Delaware corporations are subject to Delaware s business combination statute. In general, such statute prohibits a corporation from engaging in any business combination transactions with an interested stockholder for a period of three years after the time that the stockholder became an interested stockholder, unless approved by the board of directors beforehand or upon satisfaction of other criteria.

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Interested Director Transactions

Under the BCBCA and our articles, a director who has a conflict of interest in any transaction must promptly disclose the nature and extent of the conflict and may not vote on any board resolutions to approve such transaction unless all directors of the corporation are interested, in which case any or all of them may vote. Excluded directors will, however, count for purposes of quorum. A director is liable to account to the corporation for any profit that accrues to the director under or as a result of the interested transaction.

Under the DGCL, a transaction in which a director of the corporation has a conflict of interest is not void or voidable solely because of the director s conflict, solely because the director is present at or participates in the meeting of the board of directors or committee which authorizes the transaction or solely because any such director s vote is counted for such purpose, if (a) the material facts of the conflict of interest are known to or disclosed to the board of directors or the committee and the board of directors or committee in good faith authorizes the transaction by a majority of the votes of the disinterested directors, (b) the material facts of the conflict of interest are known or disclosed to the stockholders of the corporation and the transaction is approved in good faith by the stockholders, or (c) the board of directors can demonstrate that the transaction is fair as to the corporation as of the time it is approved by the board of directors, committee or stockholders.

Directors and Officers Liability and Indemnification

Our articles provide that Sophiris must indemnify a director, former director or alternative director of Sophiris and his or her heirs and legal personal representatives, as set out in the BCBCA, against all eligible penalties to which such person is or may be liable, and Sophiris must, after the final disposition of an eligible proceeding, pay the expenses actually and reasonably incurred by such person in respect of that proceeding. Each director and alternate director is deemed to have contracted with Sophiris on the terms of the indemnity contained in our articles. In addition, Sophiris may indemnify any other person in accordance with the BCBCA.

Under the DGCL, a corporation has the power to indemnify any person who was, is or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, or any person who was, is or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor, in each case by reason of the fact that the person is or was a director, office, employee or agent of the corporation, against expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interest of the corporation, and subject to certain other limitations.

Oppression Remedy

The BCBCA provides an oppression remedy that enables a court to make any order, whether interim or final, to rectify matters that are oppressive or unfairly prejudicial to any shareholder, which includes a beneficial shareholder or any other person who, in the court s discretion, is a proper person to make such an application. The oppression remedy provides the court with very broad and flexible powers to intervene in corporate affairs to protect shareholders and other applicants.

The DGCL does not expressly provide for a similar remedy.

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SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there has been no U.S. public market for our common shares. Future sales of substantial amounts of common shares in the public market could adversely affect prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common shares in the public market after the restrictions lapse could adversely affect the prevailing market price for our common shares as well as our ability to raise equity capital in the future.

Based on the number of common shares outstanding as of June 30, 2013, upon completion of this offering, 16,149,869 common shares will be outstanding, assuming no exercise of the underwriters over-allotment option and no exercise of options or warrants. All of the shares sold in this offering will be freely tradable unless held by an affiliate of ours. Except as set forth below, the remaining common shares outstanding after this offering will be restricted in the United States as a result of securities laws or lock-up agreements. These remaining shares will generally become available for sale in the U.S. public market as follows:

- No restricted shares will be eligible for immediate sale upon the completion of this offering;
- 208,421 restricted shares will be eligible for sale under Rule 144 or Rule 701 90 days after the date of this offering; and
- The remainder of the restricted shares will be eligible for sale under Rule 144 or Rule 701 upon expiration of lock-up agreements at least 180 days after the date of this offering.

United States Resale Restrictions

Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not an affiliate of ours and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. Beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

- 1% of the number of our common shares then outstanding, which will equal approximately 161,499 shares immediately after this offering; or
- the average weekly trading volume of our common shares on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 held by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell our common shares that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted shares have entered into lock-up agreements as described below and their restricted shares will become eligible for sale at the expiration of the restrictions set forth in those agreements.

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Rule 701

Under Rule 701, our common shares acquired upon the exercise of currently outstanding options or pursuant to other rights granted under our stock plans may be resold by:

- persons other than affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject only to the manner-of-sale provisions of Rule 144; and
- our affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the manner-of-sale and volume limitations, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

As of June 30, 2013, options to purchase a total of 300,590 common shares were outstanding, of which 111,234 were vested. Of the total number of our common shares issuable under these options, substantially all are subject to contractual lock-up agreements with us or the underwriters described below under Lock-Up Agreements and Underwriting and will become eligible for sale at the expiration of those agreements unless held by an affiliate of ours.

Canadian Resale Restrictions

The sale of any of our common shares which constitutes a control distribution under applicable Canadian securities laws (generally a sale by a person or a group of persons holding 20% or more of our outstanding voting securities) will be subject to restrictions under applicable Canadian securities laws in addition to those restrictions noted above, unless the sale is made under an exemption from the prospectus requirement under applicable Canadian securities laws or qualified under a prospectus filed with Canadian securities regulatory authorities and there has been compliance with certain other requirements and restrictions regarding the manner of sale, payment of commissions, reporting and availability of current public information about us.

Lock-Up Agreements

We, along with our officers, directors, employees, Warburg Pincus Private Equity X, L.P. and its affiliates, and entities affiliated with Tavistock Life Sciences Co., have entered into lock-up agreements with the underwriters or otherwise agreed, subject to certain exceptions, that we and they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, or otherwise dispose of or hedge any of our common shares, any options or warrants to purchase our common shares, or any securities convertible into, or exchangeable for or that represent the right to receive our common shares, without the prior written consent of the representatives of the underwriters for a period of 180 days from the date of this prospectus. The 180-day lock-up period may be extended under certain circumstances where we release, or pre-announce a release of, our earnings shortly before or after the termination of the 180-day period, or we announce material news or a material event shortly before the termination of the 180-day period, unless the representatives of the underwriters waive, in writing, such extension. The foregoing automatic extension will not apply if the Financial Industry Regulatory Authority, Inc., or FINRA, amends or repeals NASD Rule 2711(f)(4), or otherwise provides written interpretive guidance regarding such rule, in each case, to eliminate the prohibition of any broker, dealer, or member of a national securities association from publishing or distributing any research report, with respect to the securities of an emerging growth company (as defined in the JOBS Act) prior to or after the expiration of any agreement between the broker, dealer, or member of a national securities association and the emerging growth company or its stockholders that restricts or prohibits the sale of securities held by the emerging growth company or its stockholders after the initial public offering date.

Stock Option Plan

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the common shares reserved for issuance under our stock option plan. The registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

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UNITED STATES AND CANADIAN INCOME TAX CONSIDERATIONS

U.S. Federal Income Tax Information for U.S. Holders

The following summary describes the material U.S. federal income tax consequences of the ownership and disposition of common shares purchased in this offering. The discussion set forth below is applicable to U.S. Holders (as defined below). This summary deals only with common shares held as capital assets, meaning generally, assets held for investment.

The term U.S. Holder means a beneficial owner of a common share that is, for U.S. federal income tax purposes:

- an individual citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if it (a) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (b) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

This summary does not describe all of the U.S. federal income tax consequences applicable to a U.S. Holder if such U.S. Holder is subject to special treatment under U.S. federal income tax laws, including if such U.S. Holder is:

- a dealer in securities or currencies;
- a financial institution;
- a regulated investment company;
- a real estate investment trust;
- an insurance company;
- a tax-exempt organization;
- a person holding our common shares as part of a hedging, integrated or conversion transaction, a constructive sale or a straddle;
- a trader in securities that has elected the mark-to-market method of accounting for its securities;

a person liable for alternative minimum tax;

a person who owns or is deemed to own 10% or more of our voting common shares;

a partnership or other pass-through entity for U.S. federal income tax purposes; or

a person whose functional currency is not the U.S. dollar.

If a partnership holds our common shares, the tax treatment of a partner will generally depend upon the status of the partner and the activities of the partnership. Partners of a partnership holding our common shares should consult their own tax advisors.

The discussion below is based upon the provisions of the U.S. Internal Revenue Code of 1986, as amended, or the Code, and regulations, including proposed regulations, Internal Revenue Service, or the IRS, rulings and judicial decisions thereunder as of the date hereof. These authorities may be replaced, revoked or modified so as to result in U.S. federal income tax consequences different from those discussed below. This discussion does not contain a detailed description of all U.S. federal income tax consequences applicable to a U.S. Holder in light of such U.S. Holder s particular circumstances and does not address the effects of any state, local or non-U.S. tax laws.

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If you are considering the purchase of our common shares, you should consult your own tax advisors concerning the U.S. federal income tax consequences to you in light of your particular situation as well as any consequences arising under the laws of any other taxing jurisdiction.

Taxation of Dividends

Subject to the discussion below under Passive Foreign Investment Company Consequences, the gross amount of distributions on our common shares (including amounts withheld to pay Canadian withholding taxes) will be taxable as dividends to a U.S. Holder to the extent paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Dividends paid on our common shares (including withheld taxes) will be includable in a U.S. Holder s gross income as dividend income when actually or constructively received. Such dividends will not be eligible for the dividends-received deduction generally allowed to corporations with respect to dividends received from U.S. corporations. Distributions treated as dividends that are received by non-corporate U.S. Holders are expected to qualify for the 20% reduced maximum tax rate available for dividends received from a qualified foreign corporation provided certain holding period and other requirements are met. However, if we are a PFIC for the taxable year in which the dividends are paid or the preceding taxable year (see Passive Foreign Investment Company Consequences below), we will not be treated as a qualified foreign corporation, and therefore the reduced maximum tax rate described above will not apply. Non-corporate U.S. Holders that do not meet a minimum holding period requirement during which they are not protected from the risk of loss or that elect to treat the dividend income as investment income under applicable Code provisions will not be eligible for the reduced rates of taxation regardless of our status as a qualified foreign corporation. Further, the rate reduction will not apply to dividends if the recipient of a dividend is obligated to make related payments with respect to positions in substantially similar or related property. This disallowance applies even if the minimum holding period has been met.

Subject to certain conditions and limitations, Canadian tax withheld from dividends paid on our common shares (see Canadian Federal Income Tax Information Non-Residents of Canada Dividends on the Common Shares) may be deducted by a U.S. Holder from adjusted gross income or claimed as a credit against the U.S. Holder s U.S. federal income tax. A U.S. Holder may claim a deduction for Canadian taxes withheld from dividends paid in a taxable year only if the U.S. Holder elects to deduct all foreign income taxes paid in that taxable year. A credit may only be claimed against U.S. federal income tax on foreign source income. The credit is calculated separately with respect to different categories of income. Dividends paid on our common shares will generally constitute foreign source passive category income for foreign tax credit purposes. A special rule will apply if we are a United States-owned foreign corporation. In that case, dividends paid in a taxable year will be treated as dividends from U.S. sources and foreign sources in proportion to our earnings and profits for the taxable year from U.S. sources and from foreign sources. A U.S. Holder who is eligible to claim benefits under the Treaty however, may treat the entire dividend as one from foreign sources for the purpose of claiming a credit for any Canadian withholding tax deducted from the dividend. We will be treated as a U.S.-owned foreign corporation as long as stock representing 50% or more of the voting power or value of our common shares is owned, directly or indirectly, by U.S. persons. The rules relating to the determination of foreign source income and the foreign tax credit are complex, and availability of a foreign tax credit depends on numerous factors. Each U.S. Holder should consult with its own tax advisor to determine whether its income with respect to our common shares would be foreign source income and whether and to what extent that U.S. Holder would be entitled to the foreign tax credit.

To the extent that the amount of any distribution exceeds our current and accumulated earnings and profits for a taxable year, as determined under U.S. federal income tax principles, the distribution will first be treated as a tax-free return of capital, causing a reduction in the adjusted basis of the common shares (thereby increasing the amount of gain, or decreasing the amount of loss, to be recognized on a subsequent disposition of the common shares), and the balance in excess of adjusted basis will be taxed as capital gain recognized on a sale or exchange. However, we cannot provide any assurance that we will maintain or provide earnings and profits determinations in accordance with U.S. federal income tax principles. Therefore, U.S. Holders should expect that

a distribution will generally be treated as a dividend (as discussed above) even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above.

If a distribution is paid in Canadian dollars, the U.S. dollar value of such distribution on the date of receipt is used to determine the amount of the distribution received by a U.S. Holders. A U.S. Holder who continues to hold such Canadian dollars after the date on which they are received may recognize gain or loss upon their disposition due to exchange rate fluctuations. Generally, such gains and losses will be ordinary income or loss from U.S. sources.

Taxation of Capital Gains

Subject to the discussion below under Passive Foreign Investment Company Consequences, a U.S. Holder will recognize taxable gain or loss on the sale of our common shares equal to the difference between the amount realized for the common shares and the U.S. Holder s tax basis in the common shares. Such gain or loss will be capital gain or loss. Capital gains of non-corporate U.S. Holders, including individual U.S. Holders, derived with respect to capital assets held for more than one year are eligible for reduced rates of taxation. The deductibility of capital losses is subject to limitations. Any gain or loss recognized by a U.S. Holder will generally be U.S. source gain or loss for foreign tax credit limitation purposes.

Passive Foreign Investment Company Consequences

In general, a corporation organized outside the United States will be treated as a PFIC in any taxable year in which either (i) at least 75% of its gross income is passive income or (ii) on average at least 50% of its assets is attributable to assets that produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents, and gains from commodities and currency transactions and from the sale or exchange of property that gives rise to passive income. Assets that produce or are held for the production of passive income include cash, even if held as working capital or raised in a public offering, marketable securities and other assets that may produce passive income. The average percentage of a corporation s assets that produce or are held for the production of passive income generally is determined on the basis of the fair market value of the corporation s assets at the end of each quarter. However, if the corporation is a controlled foreign corporation that is not a publicly traded corporation for the taxable year, the determination is based on the adjusted tax basis of the corporation s assets. We believe that we currently are a controlled foreign corporation and we can provide no assurance that we will not remain a controlled foreign corporation after the offering. In determining whether a foreign corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

Based on the nature of our business, the projected composition of our income and estimated fair market value of our assets, we were likely characterized as a PFIC in 2012 and we may be a PFIC in 2013 and we could be a PFIC in one or more subsequent years. Our status as a PFIC is a fact-intensive determination made on an annual basis and we cannot provide any assurance regarding our PFIC status for the current or future taxable years. Our U.S. counsel expresses no opinion with respect to our PFIC status and also expresses no opinion with respect to our expectations regarding our PFIC status.

If we are a PFIC in any taxable year during which a U.S. Holder owns our common shares, such U.S. Holder could be liable for additional taxes and interest charges upon (i) certain distributions by us (generally any distribution paid during a taxable year that is greater than 125% of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. Holder s holding period for our common shares), and (ii) any gain recognized on a sale, exchange or other disposition, including a pledge, of our common shares, whether or not we continue to be a PFIC. In these circumstances, the tax will be determined by allocating such distributions or gain ratably over the U.S. Holder s holding period for the common shares. The amount allocated to the current taxable year (i.e., the year in which the distribution occurs or the gain is recognized) and any year

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prior to the first taxable year in which we are a PFIC will be taxed as ordinary income earned in the current taxable year. The amount allocated to other taxable years in which we are a PFIC will be taxed at the highest marginal rates in effect for individuals or corporations as applicable to ordinary income for each such taxable year, and an interest charge, generally applicable to underpayments of tax, will be added to the tax. If we are a PFIC at any time when a U.S. Holder holds our common shares, we will generally continue to be treated as a PFIC with respect to the U.S. Holder for all succeeding years during which the U.S. Holder holds our

common shares even if we cease to meet the PFIC gross income test or asset test. However, if we cease to meet these tests, a U.S. Holder can avoid the continuing impact of the PFIC rules by making a special election (a Purging Election) to recognize gain in the manner described above as if our common shares had been sold on the last day of the last taxable year during which we were a PFIC. In addition, for a U.S. Holder making such an election, a new holding period would be deemed to begin for our common shares for purposes of the PFIC rules. After the Purging Election, the common shares with respect to which the Purging Election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

The tax consequences that would apply if we were a PFIC would be different from those described above if a U.S. Holder were able to make a valid qualified electing fund, or QEF, election. For each year that we meet the PFIC gross income test or asset test, an electing U.S. Holder would be required to include in gross income, its pro rata share of our net ordinary income and net capital gains, if any, as determined under U.S. federal income tax principles. The U.S. Holder s adjusted tax basis in our shares would be increased by the amount of such inclusions. An actual distribution to the U.S. Holder out of such income generally would not be treated as a dividend and would decrease the U.S. Holder s adjusted tax basis in our shares. Gain realized from the sale of our shares covered by a QEF election would be taxed as a capital gain. Generally, a QEF election must be made by the U.S. Holder in a timely filed tax return for the first taxable year in which the U.S. Holder held our shares that includes the close of our taxable year for which we met the PFIC gross income test or asset test. A QEF election is made on IRS Form 8621. U.S. Holders will be eligible to make QEF elections only if we agree to provide U.S. Holders with the information they will need to comply with the QEF rules. Because we intend to provide this information, a U.S. Holder should be eligible to make a QEF election with respect to its shares.

The tax consequences that would apply if we were a PFIC would also be different from those described above if a timely and valid mark-to-market election is made by a U.S. Holder of our common shares. An electing U.S. Holder generally would take into account as ordinary income for each year that we meet the PFIC gross income test or asset test, the excess of the fair market value of our common shares held at the end of the taxable year over the adjusted tax basis of such common shares. The U.S. Holder would also take into account, as an ordinary loss for each year that we meet the PFIC gross income test or asset test, the excess of the adjusted tax basis of such common shares over their fair market value at the end of the taxable year, but only to the extent of the aggregate of the amounts previously included in income as a result of the mark-to-market election. The U.S. Holder s tax basis in our common shares would be adjusted to reflect any income or loss resulting from the mark-to-market election. Any gain from a sale, exchange or other disposition of the common shares in any taxable year in which we are a PFIC would be treated as ordinary income and any loss from such sale, exchange or other disposition would be treated first as ordinary loss to the extent of any net mark-to-market gains previously included in income and thereafter as capital loss. If, after having been a PFIC for one or more taxable years, we cease to be classified as a PFIC, the U.S. Holder would not be required to take into account any latent gain or loss in the manner described above and any realized gain or loss would be classified as a capital gain or loss. A mark-to-market election will not apply to our common shares for any taxable year during which we are not a PFIC, but it will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any subsidiary that we own.

A mark-to-market election is available to a U.S. Holder only if the common shares are considered marketable stock. Generally, stock will be considered marketable stock if it is regularly traded on a qualified exchange within the meaning of applicable U.S. Treasury regulations. A class of stock is regularly traded during any calendar year during which such class of stock is traded, other than in de minimis quantities,

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on at least 15 days during each calendar quarter. We expect that our common shares will be marketable stock as long as they remain listed on NASDAQ and are regularly traded.

If we are a PFIC in any taxable year during which a U.S. Holder owns the common shares, such U.S. Holder may also suffer adverse tax consequences under the PFIC rules described above with respect to any lower-tier PFIC in which we have a direct or indirect equity interest.

Each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information as the U.S. Treasury may require.

The U.S. federal income tax rules relating to PFICs are complex. Prospective U.S. investors are urged to consult their own tax advisers with respect to the purchase, ownership and disposition of our common shares, the consequences to them of an investment in a PFIC, any elections available with respect to our common shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of our common shares. We cannot provide any assurance that the IRS will agree with our annual determinations of our PFIC status.

New Legislation Regarding Medicare Tax

For taxable years beginning after December 31, 2012, certain U.S. Holders who are individuals, estates or trusts will be subject to a 3.8% tax on all or a portion of their net investment income, which includes all or a portion of their dividends (or deemed dividends) on our common shares and net gains from the disposition of our common shares. Whether a U.S. Holder makes various PFIC elections with respect to our shares as described above and/or makes an income inclusion election under the proposed regulations of the Medicare tax will impact the timing of the income inclusion for purposes of the Medicare tax. U.S. Holders that are individuals, estates or trusts should consult their tax advisors regarding the applicability of the Medicare tax to any of their income or gains in respect of our common shares.

Information Reporting and Backup Withholding

In general, information reporting will apply to dividends in respect of our common shares and the proceeds from the sale or disposition of our common shares that are paid to a U.S. Holder within the United States (and in certain cases, outside the United States), unless the U.S. Holder is an exempt recipient. Backup withholding may apply to such payments if the U.S. Holder fails to provide a taxpayer identification number or certification of other exempt status or if the U.S. Holder has previously failed to report in full dividend or interest income. If backup withholding applies to a payment, we or our paying agent will deduct the amount of any required withholding directly from such payment and remit it directly to the U.S. Treasury on behalf of the U.S. Holder. Backup withholding is not an additional tax. Any amounts withheld by us or our paying agent under the backup withholding rules will be allowed as a refund or a credit against the U.S. Holder s U.S. federal income tax liability provided the required information is timely furnished to the IRS.

U.S. Holders are urged to consult with their tax advisors regarding the applicable U.S. disclosure and information reporting requirements. In certain circumstances, the failure to comply with disclosure and information reporting requirements will result in an extension of the statute of limitations on the assessment and collection of U.S. federal income taxes applicable to the U.S. Holder.

Canadian Federal Income Tax Information

The following summary describes, as of the date hereof, the principal Canadian federal income tax consequences under the Canadian Tax Act generally applicable to a holder who acquires the common shares pursuant to this offering and who, for the purposes of the Canadian Tax Act and at all relevant times, beneficially owns the common shares as capital property, and deals at arm s length with, and is not affiliated with, us, or a

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Holder. The common shares will generally be considered to be capital property for this purpose unless either the Holder holds (or will hold) such common shares in the course of carrying on a business of trading or dealing in securities, or the Holder has acquired (or will acquire) such common shares in a transaction or transactions considered to be an adventure or concern in the nature of trade.

This summary is not applicable to: (a) a Holder that is a financial institution, as defined in the Canadian Tax Act for purposes of the mark-to-market rules; (b) a Holder, an interest in which would be a tax shelter investment as defined in the Canadian Tax Act; (c) a Holder that is a specified financial institution as defined in the Canadian Tax Act; (d) a Holder that is a corporation that has elected in the prescribed form and manner and has otherwise met the requirements to use functional currency tax reporting as set out in the Canadian Tax Act; or (e) a Holder that is a corporation resident in Canada, and is, or becomes, controlled by a non-resident corporation for the purposes of the foreign affiliate dumping rules in proposed section 212.3 of the Canadian Tax Act. Any such Holder to which this summary does not apply should consult its own tax advisor.

This summary is based upon the current provisions of the Canadian Tax Act, the regulations adopted thereunder, or the Canadian Tax Regulations, and counsel s understanding of the current published administrative and assessing policies and practices of the Canada Revenue Agency. The summary also takes into account all specific proposals to amend the Canadian Tax Act and the Canadian Tax Regulations that have been publicly announced by or on behalf of the Minister of Finance (Canada) prior to the date hereof or the Canadian Tax Proposals, and assumes that all such Canadian Tax Proposals will be enacted in the form proposed. No assurance can be given that the Canadian Tax Proposals will be enacted in the form proposed or at all. This summary does not otherwise take into account or anticipate any changes in law, whether by way of legislative, judicial or administrative action or interpretation, nor does it address any provincial, territorial or foreign tax considerations.

If you are considering the purchase of our common shares, you should consult your own tax advisors concerning Canadian Federal income tax consequences to you in light of your particular situation as well as any consequences arising under the laws of any other taxing jurisdiction.

Residents of Canada

The following discussion applies to Holders who, for the purposes of the Canadian Tax Act, and at all relevant times, are residents of Canada, or Canadian Resident Holders.

Certain Canadian Resident Holders whose common shares might not otherwise qualify as capital property may, in certain circumstances, treat such common shares and every Canadian security, as defined in the Canadian Tax Act, as capital property by making an irrevocable election pursuant to subsection 39(4) of the Canadian Tax Act. Canadian Resident Holders contemplating making an subsection 39(4) election should consult their advisor for advice as to whether the election is available or advisable in their particular circumstances.

Dividends on the Common Shares

Dividends received or deemed to be received on the common shares by a Canadian Resident Holder who is an individual (other than certain trusts) will be included in income and will be subject to the gross-up and dividend tax credit rules normally applicable under the Canadian Tax Act to taxable dividends received from taxable Canadian corporations. We may designate all or a portion of such dividends as eligible dividends that are entitled to the enhanced dividend tax credit. We will notify our shareholders of any such designations at the appropriate times.

Dividends received or deemed to be received on the common shares by a Canadian Resident Holder that is a corporation will be included in its income and will generally also be deductible in computing its taxable income. A Canadian Resident Holder that is a private corporation or a subject corporation, each as defined in the Canadian Tax Act, may be liable under Part IV of the Canadian Tax Act to pay a refundable tax at a rate of 33 $^{1}/_{3}$% on dividends received or deemed to be received on the common shares to the extent such dividends are deductible in computing the Canadian Resident Holder s taxable income.

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Dispositions of the Common Shares

A disposition, or a deemed disposition, of a common share (other than to us unless purchased by us in the open market in the manner in which shares are normally purchased by any member of the public in the open market) by a Canadian Resident Holder will generally give rise to a capital gain (or a capital loss) equal to the amount by which the proceeds of disposition of the common share, net of any reasonable costs of disposition, exceed (or are less than) the adjusted cost base of the common share to the Canadian Resident Holder. For this purpose, the adjusted cost base to a Canadian Resident Holder of the common shares will be determined at any time by averaging the cost of such common shares with the adjusted cost base of any other common shares owned by the holder as capital property at that time. Such capital gain (or capital loss) will be subject to the treatment described below under Taxation of Capital Gains and Capital Losses.

Refundable Tax

A Canadian Resident Holder that is throughout the year a Canadian-controlled private Corporation, as defined in the Canadian Tax Act, may be liable to pay a refundable tax at a rate of $6\,^{2}/_{3}\%$ on certain investment income, including taxable capital gains (as defined below), but excluding dividends or deemed dividends deductible in computing taxable income.

Taxation of Capital Gains and Capital Losses

Generally, one-half of any capital gain (a taxable capital gain) realized by a Canadian Resident Holder for a taxation year must be included in the Canadian Resident Holder s income in the year. A Canadian Resident Holder is required to deduct one-half of any capital loss (an allowable capital loss) realized in the year from taxable capital gains realized in that year, and allowable capital losses in excess of taxable capital gains may be carried back and deducted in any of the three preceding taxation years, or in any subsequent year, from net taxable capital gains realized in such years (but not against other income) to the extent and under the circumstances described in the Canadian Tax Act. If the Canadian Resident Holder is a corporation, any such capital loss realized on the sale of a common share may in certain circumstances be reduced by the amount of any dividends which have been received or which are deemed to have been received on the common share. Similar rules may apply where a corporation is a member of a partnership or a beneficiary of a trust that owns shares, directly or indirectly through a partnership or a trust.

Alternative Minimum Tax

Individuals, including certain trusts, are subject to an alternative minimum tax. Generally, dividends received or deemed to be received on the common shares and capital gains realized on the disposition of common shares may increase a Canadian Resident Holder s liability for alternative minimum tax. Canadian Resident Holders should consult with their own tax advisors with respect to the potential application of the alternative minimum tax.

Non-Residents of Canada

The following discussion applies to a Holder who, for the purposes of the Canadian Tax Act, and at all relevant times, is not (and is not deemed to be) resident in Canada and will not use or hold (and will not be deemed to use or hold) the common shares in, or in the course of, carrying on a business or part of a business in Canada, or a Non-Resident of Canada Holder. In addition, this discussion does not apply to a registered non-resident insurer or an authorized foreign bank, both within the meaning of the Canadian Tax Act.

Dividends on the Common Shares

Canadian withholding tax at a rate of 25% (subject to reduction under the provisions of any applicable income tax treaty or convention) will be payable on dividends on the common shares paid or credited, or deemed to be paid or credited, to a Non-Resident of Canada Holder. The Canadian withholding taxes will be deducted

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directly by us or our paying agent from the amount of dividend otherwise payable and remitted to the Receiver General of Canada. The rate of withholding tax applicable to a dividend paid on the common shares to a Non-Resident of Canada Holder who is a resident of the U.S. for purposes of the Canada-U.S. Income Tax Convention (the Convention), beneficially owns the dividend and qualifies for the benefits of the Convention will generally be reduced to 15% or, if the Non-Resident of Canada Holder is a corporation that owns at least 10% of our voting stock, to 5%. Not all persons who are residents of the U.S. for purposes of the Convention will qualify for the benefits of the Convention. A Non-Resident Holder of Canada who is a resident of the U.S. is advised to consult its tax advisor in this regard. The rate of withholding tax on dividends is also reduced under certain other bilateral income tax treaties or conventions to which Canada is a signatory.

Dispositions of the Common Shares

A Non-Resident of Canada Holder will not be subject to tax under the Canadian Tax Act in respect of any capital gain realized by such Non-Resident of Canada Holder on a disposition of the common shares unless the common shares constitute taxable Canadian property, as defined in the Canadian Tax Act, of the Non-Resident of Canada Holder at the time of disposition and the holder is not entitled to relief under the applicable income tax treaty or convention. As long as the common shares are then listed on a designated stock exchange , which currently includes the TSX, the common shares generally will not constitute taxable Canadian property of a Non-Resident of Canada Holder, unless (a) at any time during the 60-month period preceding the disposition, (i) the Non-Resident of Canada Holder, persons not dealing at arm s length with such Non-Resident of Canada Holder or the Non-Resident of Canada Holder together with all such persons, owned 25% or more of the issued shares of any class or series of our capital stock and (ii) more than 50% of the fair market value of the common shares was derived, directly or indirectly, from a combination of real or immoveable property situated in Canada, Canadian resource property, as such term is defined in the Canadian Tax Act, timber resource property, as such terms are defined in the Canadian Tax Act, or options in respect of interests in, or for civil law rights in, any such properties whether or not the property exists, or (b) the common shares are otherwise deemed to be taxable Canadian property. If the common shares are considered taxable Canadian property to a Non-Resident of Canada Holder, an applicable income tax treaty or convention may in certain circumstances exempt that Non-Resident of Canada Holder from tax under the Canadian Tax Act in respect of the disposition of the common shares. **Non-Resident of Canada Holders whose common shares are taxable Canadian property should consult their own tax advisors for advice having regard to their particular circumstances.**

As long as the common shares are listed at the time of their disposition on the TSX or another recognized stock exchange , as defined in the Canadian Tax Act, a Non-Resident of Canada Holder who disposes of common shares that are taxable Canadian property will not be required to satisfy the obligations imposed under section 116 of the Canadian Tax Act and, as such, the purchaser of such shares will not be required to withhold any amount on the purchase price paid. An exemption from such requirements may also be available in respect of such disposition if the common shares are treaty-exempt property, as defined in the Canadian Tax Act.

Eligibility for investment

Based on the provisions of the Canadian Tax Act in force on the date hereof and the Canadian Tax Proposals, the common shares will be qualified investments for the purposes of the Canadian Tax Act at the time of their acquisition for trusts governed by registered retirement savings plans, or RRSP, registered retirement income funds, or RRIF, deferred profit sharing plans, registered education savings plans, registered disability savings plans and tax-free savings accounts, or TFSA, each as defined in the Canadian Tax Act, or collectively, the Deferred Plans, provided that at that time the common shares are listed on a designated stock exchange, within the meaning of the Canadian Tax Act (which currently includes the TSX).

Notwithstanding the foregoing, if the common shares are prohibited investments for a trust governed by a TFSA an RRSP or a RRIF, the holder of such TFSA, RRSP or a RRIF, may be subject to a penalty tax under the Canadian Tax Act. Any such security will not be a prohibited investment for a particular trust governed by a

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TFSA, RRSP or a RRIF, provided the holder deals at arm s length with us for purposes of the Canadian Tax Act and does not have a significant interest, within the meaning of the Canadian Tax Act, in us or any person or partnership with which we do not deal at arm s length for purposes of the Canadian Tax Act. Prospective investors should consult their tax advisors for advice as to whether the common shares will be prohibited investments in their particular circumstances.

Prospective subscribers who intend to hold the common shares in Deferred Plans are advised to consult their tax advisors.

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UNDERWRITING

Citigroup Global Markets Inc. and Leerink Swann LLC are acting as joint book-running managers of the offering and as representatives of the underwriters named below. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, each underwriter named below has severally agreed to purchase, and we have agreed to sell to that underwriter, the number of shares set forth opposite the underwriter s name.

Underwriter	Number of Shares
Citigroup Global Markets Inc.	5,720,000
Leerink Swann LLC	4,030,000
Stifel, Nicolaus & Company, Incorporated	1,950,000
Lazard Capital Markets LLC	1,300,000
Total	13,000,000

The underwriting agreement provides that the obligations of the underwriters to purchase the shares included in this offering are subject to approval of legal matters by counsel and to other conditions, including, but not limited to, the receipt of approval of the Toronto Stock Exchange. The underwriters are obligated to purchase all the shares (other than those covered by the over-allotment option described below) if they purchase any of the shares.

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount from the initial public offering price not to exceed $0.2100 per share. If all the shares are not sold at the initial offering price, the underwriters may change the offering price and the other selling terms. The representatives have advised us that the underwriters do not intend to make sales to discretionary accounts.

The underwriters expect that delivery of the common shares will be made against payment therefor on or about August 23, 2013, which will be the fifth business day following the date of this prospectus (this settlement cycle being referred to as T+5). Under Rule 15c6-1 of the Exchange Act, trades in the secondary market generally are required to settle in three business days, unless the parties to any such trade expressly agree otherwise. Accordingly, purchasers who wish to trade the common shares on the date of this prospectus or the next succeeding business day will be required, by virtue of the fact that the common shares initially will settle in T+5, to specify an alternate settlement cycle at the time of any such trade to prevent a failed settlement and should consult their own advisor.

If the underwriters sell more shares than the total number set forth in the table above, we have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares at the public offering price less the underwriting discount. The underwriters may exercise the option solely for the purpose of covering over-allotments, if any, in connection with this offering. To the extent the option is exercised, each underwriter must purchase a number of additional shares approximately proportionate to that underwriter s initial purchase commitment. Any shares issued or sold under the option will be issued and sold on the same terms and conditions as the other shares that are the subject of this offering.

We, our officers, directors and employees and certain of our other shareholders have agreed that, for a period of 180 days from the date of this prospectus, we and they will not, without the prior written consent of Citigroup Global Markets Inc. and Leerink Swann LLC, dispose of or hedge any shares or any securities convertible into or exchangeable for our common shares. Citigroup Global Markets Inc. and Leerink Swann LLC in their sole discretion may release any of the securities subject to these lock-up agreements at any time, which, in the case of officers and directors, shall be with notice.

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Prior to this offering, there has been no U.S. public market for our shares. Consequently, the initial public offering price for the shares was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our results of operations, our current financial condition, our future prospects, our markets, the economic conditions in and future prospects for the industry in which we compete, our management, and currently prevailing general conditions in the U.S. equity securities markets, including current market valuations of U.S. publicly traded companies considered comparable to our company. We cannot assure you, however, that the price at which the shares will sell in the public market after this offering will not be lower than the initial public offering price or that an active U.S. trading market in our shares will develop and continue after this offering.

We have applied to have our shares listed on the NASDAQ Global Market under the symbol SPHS.

The following table shows the underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters over-allotment option.

	Paid by Sophiris Bio Inc.	
	No Exercise	**Full Exercise**
Per share	$ 0.35	$ 0.35
Total	$ 4,550,000	$ 5,232,500

We estimate that our portion of the total expenses of this offering will be $3.5 million.

We have also agreed to reimburse the underwriters for certain of their expenses in an amount up to $55,000 as set forth in the underwriting agreement.

In connection with the offering, the underwriters may purchase and sell shares in the open market. Purchases and sales in the open market may include short sales, purchases to cover short positions, which may include purchases pursuant to the over-allotment option, and stabilizing purchases.

Short sales involve secondary market sales by the underwriters of a greater number of shares than they are required to purchase in the offering.

Covered short sales are sales of shares in an amount up to the number of shares represented by the underwriters over-allotment option.

Naked short sales are sales of shares in an amount in excess of the number of shares represented by the underwriters over-allotment option.

Covering transactions involve purchases of shares either pursuant to the underwriters over-allotment option or in the open market in order to cover short positions.

To close a naked short position, the underwriters must purchase shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

To close a covered short position, the underwriters must purchase shares in the open market or must exercise the over-allotment option. In determining the source of shares to close the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may

purchase shares through the over-allotment option.

Stabilizing transactions involve bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum.

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Purchases to cover short positions and stabilizing purchases, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the shares. They may also cause the price of the shares to be higher than the price that would otherwise exist in the open market in the absence of these transactions. The underwriters may conduct these transactions on the NASDAQ Global Market, in the over-the-counter market or otherwise. If the underwriters commence any of these transactions, they may discontinue them at any time.

Affiliations

The underwriters are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. The underwriters and their respective affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (which may include bank loans and/or credit default swaps) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

Lazard Frères & Co. LLC referred this transaction to Lazard Capital Markets LLC and will receive a referral fee from Lazard Capital Markets LLC in connection therewith.

Notice to Prospective Investors in the European Economic Area

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a relevant member state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of shares described in this prospectus may not be made to the public in that relevant member state other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the relevant member state has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the relevant Dealer or Dealers nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For purposes of this provision, the expression an offer of securities to the public in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe for the shares, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, and the expression Prospectus Directive means Directive 2003/71/EC (and amendments thereto,

including the 2010 PD Amending Directive, to the extent implemented in the relevant member state) and includes any relevant implementing measure in the relevant member state. The expression 2010 PD Amending Directive means Directive 2010/73/EU.

The sellers of the shares have not authorized and do not authorize the making of any offer of shares through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the shares as contemplated in this prospectus. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of the shares on behalf of the sellers or the underwriters.

Notice to Prospective Investors in the United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order, or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order, each such person being referred to as a relevant person. This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Prospective Investors in France

Neither this prospectus nor any other offering material relating to the shares described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers.* The shares have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the shares has been or will be:

released, issued, distributed or caused to be released, issued or distributed to the public in France; or

used in connection with any offer for subscription or sale of the shares to the public in France.

Such offers, sales and distributions will be made in France only:

- to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d investisseurs*), in each case investing for their own account, all as defined in, and in accordance with articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French *Code monétaire et financier*;

- to investment services providers authorized to engage in portfolio management on behalf of third parties; or

- in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French *Code monétaire et financier* and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des Marchés Financiers*, does not constitute a public offer (*appel public à l épargne*).

The shares may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French *Code monétaire et financier*.

Notice to Prospective Investors in Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to professional investors within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a prospectus within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares may be issued or

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may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Notice to Prospective Investors in Japan

The shares offered in this prospectus have not been and will not be registered under the Financial Instruments and Exchange Law of Japan. The shares have not been offered or sold and will not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan (including any corporation or other entity organized under the laws of Japan), except (i) pursuant to an exemption from the registration requirements of the Financial Instruments and Exchange Law and (ii) in compliance with any other applicable requirements of Japanese law.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than S$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;

- where no consideration is or will be given for the transfer; or

- where the transfer is by operation of law.

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Notice to Prospective Investors in Australia

No prospectus or other disclosure document (as defined in the Corporations Act 2001 (Cth) of Australia, or the Corporations Act) in relation to the common shares has been or will be lodged with the Australian Securities & Investments Commission or the ASIC. This document has not been lodged with ASIC and is only directed to certain categories of exempt persons. Accordingly, if you receive this document in Australia:

(a) you confirm and warrant that you are either:

(i) a sophisticated investor under section 708(8)(a) or (b) of the Corporations Act;

(ii) a sophisticated investor under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant s certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;

(iii) a person associated with the company under section 708(12) of the Corporations Act; or

(iv) a professional investor within the meaning of section 708(11)(a) or (b) of the Corporations Act, and to the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this document is void and incapable of acceptance; and

(b) you warrant and agree that you will not offer any of the shares for resale in Australia within 12 months of the common shares being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Notice to Prospective Investors in Chile

The shares are not registered in the Securities Registry (Registro de Valores) or subject to the control of the Chilean Securities and Exchange Commission (Superintendencia de Valores y Seguros de Chile). This prospectus and other offering materials relating to the offer of the shares do not constitute a public offer of, or an invitation to subscribe for or purchase, the shares in the Republic of Chile, other than to individually identified purchasers pursuant to a private offering within the meaning of Article 4 of the Chilean Securities Market Act (Ley de Mercado de Valores) (an offer that is not addressed to the public at large or to a certain sector or specific group of the public).

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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. The underwriters are being represented by Latham & Watkins LLP, San Diego, California. Blake, Cassels & Graydon LLP is acting as Canadian counsel to the underwriters.

EXPERTS

The consolidated financial statements as of December 31, 2012 and for the year ended December 31, 2012 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP (U.S.), an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The consolidated balance sheet as of December 31, 2011, the consolidated statements of operations and comprehensive loss and of cash flows for the year ended December 31, 2011 and the related consolidated statement of shareholders equity (deficit) for the years ended December 31, 2002 through December 31, 2011, included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP (Canada), an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

MARKET AND INDUSTRY DATA

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

WHERE YOU CAN FIND MORE INFORMATION

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

You can read our SEC filings, including the registration statement, over the Internet at the SEC s website at 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.

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Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at *www.sophirisbio.com*, at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website incorporated by reference in, and is not part of, this prospectus.

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Sophiris Bio Inc.

(A Development Stage Company)

Index to the Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Sophiris Bio Inc.

In our opinion, the accompanying consolidated balance sheet as of December 31, 2012 and the related consolidated statements of operations and comprehensive loss, of shareholders equity (deficit) and of cash flows for the year ended December 31, 2012 present fairly, in all material respects, the financial position of Sophiris Bio Inc. and its subsidiaries (a development stage company) at December 31, 2012, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

The accompanying financial statements have been prepared assuming that Sophiris Bio Inc. and its subsidiaries will continue as a going concern. As discussed in Note 1 to the financial statements, Sophiris Bio Inc. and its subsidiaries have incurred losses and negative cash flows from operations and have an accumulated deficit at December 31, 2012 that raise substantial doubt about their ability to continue as a going concern. Management s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PricewaterhouseCoopers LLP

San Diego, California

February 14, 2013, except for the effects of the share consolidation described in Note 1, as to which the date is August 12, 2013

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Sophiris Bio Inc.

We have audited the accompanying consolidated balance sheet of Sophiris Bio Inc. and its subsidiaries (a development stage company) as of December 31, 2011 and the related consolidated statements of operations and comprehensive loss, and consolidated statement of cash flows for the year ended December 31, 2011, and the related consolidated statement of shareholders equity (deficit) for the years December 31, 2002 through December 31, 2011. Management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. Our audit of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall consolidated financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the accompanying consolidated financial statements referred to above present fairly, in all material respects, the financial position of Sophiris Bio Inc. and its subsidiaries (a development stage company) as of December 31, 2011 and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ PricewaterhouseCoopers LLP

Chartered Accountants

Vancouver, BC

December 7, 2012, except for the effects of the share consolidation described in Note 1, as to which the date is August 12, 2013

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Sophiris Bio Inc.

(A Development Stage Company)

Consolidated Balance Sheets

(In thousands, expect share amounts)

(Amounts in U.S. dollars, except share amounts)

	December 31, 2011	December 31, 2012	June 30, 2013 (unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 23,410	$ 9,721	$ 3,570
Other receivables	239	71	79
Deferred financing costs		937	2,243
Prepaid expenses	586	593	333
Total current assets	24,235	11,322	6,225
Property and equipment, net	220	163	123
Intangible assets, net	316		
Other long-term assets	29	44	
Total assets	$ 24,800	$ 11,529	$ 6,348
Liabilities			
Current liabilities:			
Accounts payable	$ 2,516	$ 1,774	$ 2,007
Accrued expenses	585	2,839	2,029
Current portion of promissory notes	3,190	5,895	6,180
Total current liabilities	6,291	10,508	10,216
Long-term promissory notes, less current portion	11,512	6,126	3,171
Total liabilities	17,803	16,634	13,387
Commitments and contingencies (Note 15)			
Shareholders equity (deficit):			
Common shares, unlimited authorized shares, no par value; 2,749,228 shares issued and outstanding at December 31, 2011 and 3,149,869 shares issued and outstanding at December 31, 2012 and June 30, 2013	45,727	54,215	54,215
Common share purchase warrants	4,177	6,045	6,045
Right to invest	4,142		
Contributed surplus	5,632	8,379	8,904
Accumulated other comprehensive (loss) gain	(177)	(46)	253
Deficit accumulated during development stage	(52,504)	(73,698)	(76,456)
Total shareholders equity (deficit)	6,997	(5,105)	(7,039)

Total liabilities and shareholders equity (deficit)	$ 24,800	$ 11,529	$ 6,348

The accompanying notes are an integral part of these consolidated financial statements.

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Sophiris Bio Inc.

(A Development Stage Company)

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, expect share and per share amounts)

(Amounts in U.S. dollars, except share amounts)

	For the years ended December 31,		For the six months ended June 30,		Cumulative period from January 11, 2002 (date of inception) to June 30, 2013 (unaudited)
	2011	2012	2012 (unaudited)	2013 (unaudited)	
Revenue					
License revenue	$	$	$	$ 5,000	$ 8,000
Operating expenses					
Research and development	8,660	13,523	6,783	4,025	53,671
General and administrative	4,635	5,685	2,362	2,126	26,604
Total operating expenses	13,295	19,208	9,145	6,151	80,275
Other income (expense)					
Interest income (expense), net	(895)	(1,880)	(1,004)	(751)	(2,664)
Other income (expense), net	(11)	(106)	(84)	(356)	(702)
Total other income (expense)	(906)	(1,986)	(1,088)	(1,107)	(3,366)
Net loss before income taxes	(14,201)	(21,194)	(10,233)	(2,258)	(75,641)
Income tax expense				(500)	(815)
Net loss	$ (14,201)	$ (21,194)	(10,233)	(2,758)	$ (76,456)
Basic and diluted loss per share	$ (6.05)	$ (6.94)	$ (3.46)	$ (0.88)	
Weighted average number of outstanding shares-basic and diluted	2,345	3,054	2,956	3,150	
Other comprehensive income (loss)					
Currency translation adjustment	14	131	(103)	299	253
Total comprehensive loss	$ (14,187)	$ (21,063)	$ (10,336)	$ (2,459)	$ (76,203)

The accompanying notes are an integral part of these consolidated financial statements.

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Sophiris Bio Inc.

(A Development Stage Company)

Consolidated Statements of Shareholders Equity (Deficit)

(In thousands, expect share amounts)

(Amounts in U.S. dollars, except share amounts)

	Preferred Shares		Common Shares					Deficit Accumulated During the	Accumulated Other Comprehensive	
	Shares	Amount	Shares	Amount	Contributed Surplus	Common Share Purchase Warrants	Right to Invest	Development Stage	Income (Loss)	Total Shareholders Equity
Balance at January 11, 2002 (date of inception)		$		$	$	$	$	$	$	$
Issuance of common shares			2							
Net loss								(13)		(13)
Other comprehensive loss										
Balance at December 31, 2002			2					(13)		(13)
Issuance of common shares			110,450	146						146
Issuance of common shares, net of shares issuance costs of $74			39,742	603		46				649
Issuance of Series I Class A preferred shares, net of shares issuance costs of $6	31,985	454								454
Issuance of Series I Class A preferred shares to settle accounts payable	2,459	36								36
Stock-based compensation expense					57					57
Net loss								(333)		(333)
Other comprehensive income									112	112
Balance at December 31, 2003	34,444	490	150,194	749	57	46		(346)	112	1,108
Issuance of common shares, net of shares issuance costs of $63			37,081	612		53				665
Issuance of common shares upon conversion of preferred shares	(34,444)	(490)	62,625	526						36
Reverse acquisition of SNB			111,914	465	314					779
Issuance of common shares in public offering, net of stock issuance costs of $522			86,116	2,568		460				3,028
Common share purchase warrants issued for agent s commission				(117)		114				(3)
Exercise of common share purchase warrants			323	14		(5)				9
Exercise of common share purchase options			2,981	105	(60)					45
Stock-based compensation expense					116					116
Net loss								(2,293)		(2,293)
Other comprehensive income									140	140
Balance at December 31, 2004			451,234	4,922	427	668		(2,639)	252	3,630
Exercise of common share purchase warrants			446	15		(6)				9
Exercise of common share purchase options			1,501	65	(35)					30

Expiration of common share purchases warrants			479	(479)			
Issuance of common shares for license	5,131	155					155
Issuance of common shares pursuant to private placement, net of stock issuance costs of $212	225,838	2,946		1,782			4,728
Stock-based compensation expense			556				556
Net loss					(4,580)		(4,580)
Other comprehensive income						62	62
Balance at December 31, 2005	684,150	8,103	1,427	1,965	(7,219)	314	4,590

The accompanying notes are an integral part of these consolidated financial statements.

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Sophiris Bio Inc.

(A Development Stage Company)

Consolidated Statements of Shareholders Equity (Deficit)

(In thousands, expect share amounts)

(Amounts in U.S. dollars, except share amounts)

	Preferred Shares	Common Shares					Deficit Accumulated During the	Accumulated Other Comprehensive	Total
	Shares Amount	Shares	Amount	Contributed Surplus	Common Share Purchase Warrants	Right to Invest	Development Stage	Income (Loss)	Shareholders Equity
Balance at December 31, 2005		684,150	8,103	1,427	1,965		(7,219)	314	4,590
Exercise of common share purchase warrants		6,336	242		(97)				145
Expiration of common share purchase warrants				136	(136)				
Exercise of common share options		741	24	(20)					4
Issuance of common shares pursuant to private placement, net of stock issuance costs of $832		390,375	6,650		1,437				8,087
Stock-based compensation expense				437					437
Net loss							(4,418)		(4,418)
Other comprehensive loss								(97)	(97)
Balance at December 31, 2006		1,081,602	15,019	1,980	3,169		(11,637)	217	8,748
Exercise of common share purchase warrants		230,887	9,997		(1,812)				8,185
Expiration of common share purchase warrants				27	(27)				
Exercise of common stock options		1,859	125	(35)					90
Issuance of common shares for intangible asset acquisition		2,458	110						110
Stock-based compensation expense				435					435
Net loss							(6,928)		(6,928)
Other comprehensive income								662	662
Balance at December 31, 2007		1,316,806	25,251	2,407	1,330		(18,565)	879	11,302
Exercise of common share purchase warrants		558	23		(4)				19
Expiration of common share purchase warrants				1,342	(1,354)				(12)
Exercise of common stock options		7,627	138	(64)					74
Issuance of common shares pursuant to private placement, net of stock issuance costs of $523		134,510	4,266		160				4,426
Common shares issued as finance fee, net of issuance costs of $69									
Common share purchase warrants issued for commission									
Stock-based compensation expense				390					390
Net loss							(8,369)		(8,369)
Other comprehensive loss								(1,935)	(1,935)

Balance at December 31, 2008	1,459,501	29,678	4,075	132	(26,934)	(1,056)	5,895
Exercise of common share purchase warrants	881	17		(6)			11
Issuance of common shares and common share purchase warrants, net of issuance costs of $274	164,500	1,689		64			1,753
Common share purchase warrants issued for commission							
Stock-based compensation expense			297				297
Net loss					(6,957)		(6,957)
Other comprehensive income						496	496
Balance at December 31, 2009	1,624,882	31,384	4,372	190	(33,891)	(560)	1,495

The accompanying notes are an integral part of these consolidated financial statements.

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Sophiris Bio Inc.

(A Development Stage Company)

Consolidated Statements of Shareholders Equity (Deficit)

(In thousands, expect share amounts)

(Amounts in U.S. dollars, except share amounts)

	Preferred Shares		Common Shares					Deficit Accumulated During the	Accumulated Other	
	Shares	Amount	Shares	Amount	Contributed Surplus	Common Share Purchase Warrants	Right to Invest	Development Stage	Comprehensive Income (Loss)	Total Shareholders Equity (Deficit)
Balance at December 31, 2009			1,624,882	31,384	4,372	190		(33,891)	(560)	1,495
Exercise of common share purchase warrants			10,080	240		(99)				141
Exercise of employee stock options			142	3		(1)				2
Expiration of common share purchase warrants					99	(99)				
Issuance of common shares and common share purchase warrants, net of issuance costs of $1,548			697,796	5,202		1,827	6,214			13,243
Stock-based compensation expense					457					457
Net loss								(4,412)		(4,412)
Other comprehensive income									369	369
Balance at December 31, 2010			2,332,900	36,829	4,928	1,818	6,214	(38,303)	(191)	11,295
Exercise of common share purchase warrants			4,860	101		(24)				77
Exercise of employee stock options			10,827	514	(211)					303
Issuance of warrants with secured promissory notes						519				519
Issuance of common shares and common share purchase warrants, net of issuance costs of $63			400,641	8,283		1,864	(2,072)			8,075
Stock-based compensation expense					915					915
Net loss								(14,201)		(14,201)
Other comprehensive income									14	14
Balance at December 31, 2011			2,749,228	45,727	5,632	4,177	4,142	(52,504)	(177)	6,997
Issuance of common shares and common share purchase warrants, net of issuance costs			400,641	8,488		1,868	(2,071)			8,285

of $66								
Expiration of right to invest			2,071	(2,071)				
Stock-based compensation expense			676					676
Net loss						(21,194)		(21,194)
Other comprehensive income							131	131
Balance at December 31, 2012	3,149,869	54,215	8,379	6,045		(73,698)	(46)	(5,105)
Stock-based compensation expense (unaudited)			525					525
Net loss (unaudited)						(2,758)		(2,758)
Other comprehensive income (unaudited)							299	299
Balance at June 30, 2013 (unaudited)	$ 3,149,869	$ 54,215	$ 8,904	$ 6,045	$	$ (76,456)	$ 253	$ (7,039)

The accompanying notes are an integral part of these consolidated financial statements.

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Sophiris Bio Inc.

(A Development Stage Company)

Consolidated Statements of Cashflows

(In thousands, expect share amounts)

(Amounts in U.S. dollars, except share amounts)

	For the years ended December 31,		For the six months ended June 30,		Cumulative period from January 11, 2002 (date of inception) to June 30, 2013 (unaudited)
	2011	2012	2012 (unaudited)	2013 (unaudited)	
Cash flows used in operating activities					
Net loss for the period	$ (14,201)	$ (21,194)	$ (10,233)	$ (2,758)	$ (76,456)
Adjustments to reconcile net loss to net cash used in operating activities:					
Stock-based compensation	915	676	344	525	4,863
Accretion of debt discount	221	509	264	208	937
Depreciation of property and equipment	44	82	40	42	565
Amortization of intangible assets	202	149	99		1,205
Amortization of promissory note issuance costs	69	155	80	61	285
Impairment loss		176			176
Foreign exchange (gain) loss	(209)	(148)	43	388	(1,282)
Loss on disposal of assets	12	1			25
Other					182
Change in operating assets and liabilities:					
Other receivables	73	172	123	35	21
Prepaid expenses	(642)	(162)	184	198	(605)
Deferred financing costs		(936)			(936)
Other long-term assets	(30)	(15)	(6)		(44)
Accounts payable and accrued expenses	1,204	1,488	126	(839)	3,492
Net cash flows used in operating activities	(12,342)	(19,047)	(8,936)	(2,140)	(67,572)
Cash flows used in investing activities					
Purchase of property and equipment	(265)	(26)	(21)	(3)	(725)
Proceeds from the disposal of property and equipment	11				11
Acquisition of intangible assets					(1,372)
Maturity of marketable securities					1,112
Purchases of marketable securities					(1,112)
Net cash flows used in investing activities	(254)	(26)	(21)	(3)	(2,086)
Cash flows from financing activities					
Issuance of common shares from private placement, net of issuance costs	8,137	8,285	8,285		50,179
Issuance of common shares from public offering, net of issuance costs					3,028
Issuance of preferred shares, net of issuance costs					465
Cash acquired on reverse acquisition					818

Issuance of common shares on exercise of warrants	77				8,702
Issuance of common shares on exercise of stock options	303				514
Cash received from the issuance of promissory notes	15,000				15,000
Principal payments on notes payable		(3,190)	(445)	(2,878)	(6,067)
Increase in lease obligations					120
Capital lease payments					(120)
Deferred financing costs				(1,040)	(1,040)
Other					4
Net cash provided by (used in) financing activities	23,517	5,095	7,840	(3,918)	71,603
Effect of exchange rate changes on cash and cash equivalents	108	289	(141)	(90)	1,625
Net increase (decrease) in cash and cash equivalents	11,029	(13,689)	(1,257)	(6,151)	3,570
Cash and cash equivalents Beginning of the period	12,381	23,410	23,410	9,721	
Cash and cash equivalents End of the period	$ 23,410	$ 9,721	$ 22,153	$ 3,570	$ 3,570
Supplemental disclosure of cash flows					
Cash paid for interest	$ 542	$ 1,350	$ 713	$ 505	
Cash paid for taxes	$	$	$	$ 500	

The accompanying notes are an integral part of these consolidated financial statements.

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Sophiris Bio Inc.

(A Development Stage Company)

Notes to The Consolidated Financial Statements

1. Nature of the business, liquidity risk and going concern

Company

Sophiris Bio Inc. (the Company or Sophiris) is a clinical-stage biopharmaceutical development stage company. The Company is currently developing PRX302 for treatment of the symptoms of benign prostatic hyperplasia (BPH or enlarged prostate). The Company is incorporated under the Company Act of British Columbia. The Company began operations on January 11, 2002. The Company s operations were initially located in Vancouver, British Columbia. In April 2011, the Company relocated its core activities and headquarters from Vancouver, British Columbia to San Diego, California. Effective April 2, 2012, the Company changed its name from Protox Therapeutics Inc. to Sophiris Bio Inc.

Since its inception, the Company has devoted substantially all of its efforts to research and development, recruiting management and technical staff, acquiring assets and raising capital. In addition, the Company has not begun to commercialize or generate revenues from any product candidate. Accordingly, the Company is considered to be in the development stage, as defined in Accounting Standards Codification (ASC) 915-10.

The consolidated financial statements include the accounts of Sophiris Bio Inc. and its wholly-owned subsidiaries, Sophiris Bio Corp. and Sophiris Bio Holding Corp., both of which are incorporated in the state of Delaware.

Liquidity

The consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The Company has incurred significant operating losses since inception and has relied on its ability to fund its operations through private and public equity financings and a debt financing. For the year ended December 31, 2012 and the six months ended June 30, 2013, the Company incurred a net loss of $21.2 million and $2.8 million, respectively, and used $19.0 million and $2.1 million of cash in operations, respectively. At December 31, 2012 and June 30, 2013, the Company had $9.7 million and $3.6 million, respectively, in cash.

Going Concern

As of June 30, 2013, substantial doubt exists over the Company s ability to continue as a going concern. As of June 30, 2013, the Company had cash of $3.6 million, accounts payable and accrued expenses of $4.0 million and the Company owes $9.3 million on its outstanding promissory notes. The Company expects to have sufficient cash to fund operations for current commitments, assuming the exclusion of the amounts due to Oxford, into September 2013. If the Company is unable to obtain financing prior to September 30, 2013, it will need to consider the possibility of ceasing operations entirely. In an effort to reduce its cash burn, on July 31, 2013, the Company entered into a second amendment to the Oxford Loan which authorized it to make an interest only payment on August 1, 2013 on its outstanding promissory note balance. The Company will resume making principal and interest payments on September 1, 2013 in accordance with the terms of the second amendment. The Company may enter into a future amendment to defer principal payments with Oxford in an effort to extend its cash runway, but the Company cannot guarantee that it will be able to enter into such an amendment. Future financing will be required prior to the initiation of the Company s first Phase 3 study which the Company plans to initiate in the second half of 2013, assuming additional financing is obtained. The Company may obtain additional financing in the future through the issuance of securities in this public offering or another public or private financing, the issuance of debt instruments and/or through a drug development partnership with a biotechnology or pharmaceutical company. The Company cannot be certain that additional funding will be

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available to the Company on acceptable terms, or at all. If the going concern assumption is not appropriate for these financial statements, then adjustments would be necessary to the carrying value of assets and liabilities, and the reported net losses and balance sheet classifications used. Such adjustments could be material to the financial statements. As the Company continues to incur losses, transition to profitability is dependent upon the successful development, approval, and commercialization of its product candidate and achieving a level of revenue adequate to support the Company s cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital.

Share Consolidation

On August 9, 2013, the Company s board of directors approved a 52-for-1 share consolidation of the Company s issued and outstanding common shares, subject to approval by the Toronto Stock Exchange. Accordingly, all share and per share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively to reflect the share consolidation. The Company s stock option plan and outstanding warrants provide for a pro-rata adjustment to the number of shares issuable upon the exercise of outstanding stock options and warrants in the event of a share consolidation. The effects of the share consolidation have been given retroactive effect to the related disclosures of outstanding stock options and warrants.

2. Summary of significant accounting policies

Significant accounting policies followed by the Company in the preparation of its consolidated financial statements are as follows:

Basis of consolidation

The consolidated financial statements include the accounts of the Company, Sophiris Bio Corp. and Sophiris Bio Holding Corp. All intercompany balances and transactions have been eliminated for purposes of consolidation.

Basis of presentation and use of estimates

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (GAAP). GAAP requires the Company s management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. The Company bases estimates and judgments on historical experience and on various other factors that it believes to be reasonable under the circumstances. The significant estimates in these consolidated financial statements include revenue recognition, stock-based compensation expense, functional currency, and accrued research and development expenses, including accruals related to the Company s ongoing clinical trial. The Company s actual results may differ from these estimates under different assumptions or conditions. The Company evaluates its estimates on an ongoing basis. Changes in estimates are reflected in reported results in the period in which they become known by the Company s management.

Unaudited Interim Financial Information

The accompanying interim balance sheet as of June 30, 2013 and the statements of operations and comprehensive loss and cash flows for the six months ended June 30, 2012 and 2013 and the statements of shareholders equity (deficit) for the six months ended June 30, 2013 and the footnote disclosures are unaudited. These unaudited interim financial statements have been prepared in accordance with GAAP. In management s opinion, the unaudited interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company s financial position as of June 30, 2013 and its results of operations and comprehensive loss and its cash flows for the six months ended June 30, 2012 and 2013. The results for the six months ended June 30, 2013 are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

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Foreign currency

Functional currency

The functional currency of Sophiris Bio Inc. is the Canadian dollar and the functional currency of Sophiris Bio Corp. and Sophiris Bio Holding Corp. is the U.S. dollar.

Reporting currency

The consolidated financial statements have been presented in a currency other than the parent s functional currency as management has determined that the U.S. dollar is the common currency in which the Company s peers, being international drug and pharmaceutical companies, present their financial statements. For presentation purposes the assets and liabilities of the Company are translated to U.S. dollars at exchange rates at the reporting date. The historical equity transactions have been translated using historical rates in effect on the date that each transaction occurred. The income and expenses are translated to U.S. dollars at the average exchange rate for the period in which the transaction arose. Exchange differences arising are recognized in a separate component of equity titled accumulated other comprehensive income (loss).

Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of foreign currency transactions and from the remeasurement of monetary assets and liabilities denominated in currencies other than an entities functional currency are recognized as a component of other income (expense), net.

Cash and cash equivalents

Cash equivalents are short-term, highly liquid investments with an original maturity of three months or less at the date of purchase.

Concentration of credit risk

Financial instruments that subject the Company to credit risk consist primarily of cash and cash equivalents. The Company places its cash and cash equivalents in accredited financial institutions and therefore the Company s management believes these funds are subject to minimal credit risk. The Company has no significant off-balance sheet concentrations of credit risk such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Fair value of financial instruments

The Company measures certain financial assets and liabilities at fair value based on the exchange price that would be received for an asset or paid for to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants. The carrying amounts of the Company s financial instruments, including cash and cash equivalents, and accounts payable and accrued expenses, approximate fair value due to their short maturities.

Deferred financing costs

Deferred financing costs represent direct costs associated with the future issuance of the Company s corporate securities. Direct costs include but are not limited to the legal, accounting and printer costs. Indirect costs such as management salaries associated with the future issuance of corporate securities are expensed as incurred. Upon the completion of the proposed issuance of corporate securities, the deferred financing costs will be offset against the proceeds from the securities issuance. If the proposed issuance is not completed, the deferred financing costs will be charged to expense.

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Property and equipment

Property and equipment are recorded at cost and depreciated using the straight-line method, based on their estimated useful lives as follows:

Asset classification	Estimated useful life (in years)
Equipment	3-5
Computer hardware	3
Software	3-5
Leasehold improvements	Lesser of useful life or lease term
Furniture and fixtures	5

Repairs and maintenance costs are expensed as incurred.

The Company reviews its long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. If impairment is indicated, the asset will be written down to its estimated fair value on a discounted cash flow basis. The Company has not recognized any impairment losses through December 31, 2012.

Promissory notes

Promissory notes are recognized initially at fair value. Promissory notes are subsequently carried at amortized cost; any difference between the proceeds and the redemption value is recognized in the statement of operations and comprehensive loss over the period of the notes payable using the effective interest method.

The fair value of the promissory notes when issued with equity is recognized initially at the fair value of similar promissory notes issued on a standalone basis. The equity that is issued with borrowings is valued at fair value using the Black-Scholes valuation model.

Debt issuance costs, net

Debt issuance costs, net, represent legal and other direct costs related to the Company s promissory notes. These costs were recorded as debt issuance costs on the balance sheets at the time they were incurred, and are being amortized to interest expense utilizing the effective interest method through the earliest date at which the Company can be required to repay the notes.

Revenue recognition

The Company may enter into product development agreements with collaborative partners for the research and development of products for the treatment of urological diseases. The terms of the agreements may include nonrefundable signing and licensing fees, milestone payments and royalties on any product sales derived from collaborations. These multiple element arrangements are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. License fees are recognized as revenue when persuasive evidence of an arrangement exists, the fee is fixed or determinable, delivery or performance has substantially completed and collection is reasonably assured.

The Company recognizes up front license payments as revenue upon delivery of the license only if the license has stand-alone value to the customer and if the agreement includes a general right of return, the delivery or performance of undelivered items is considered probable and within the control of the Company. The payment is generally allocated to the separate units of accounting based on their relative selling prices. The selling price of each deliverable is determined using vendor specific objective evidence of selling prices, if it exists; otherwise, third-party evidence of selling prices. If neither vendor specific objective evidence or third-party evidence exists, the

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Company uses its best estimate of the selling price for each deliverable. The payment allocated is limited to the amount that is not contingent on the delivery of additional items or fulfillment of other performance conditions.

Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized. If the Company cannot reasonably estimate the timing and the level of effort to complete its performance obligations under the arrangement, then revenue under the arrangement is recognized on a straight-line basis over the period the Company is expected to complete its performance obligations.

The Company evaluates milestone payments on an individual basis and recognizes revenue from non-refundable milestone payments when the earnings process is complete and the payment is reasonably assured. Non-refundable milestone payments related to arrangements under which the Company has continuing performance obligations are recognized as revenue upon achievement of the associated milestone, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with the milestone event. Any amounts received under agreements in advance of performance, if deemed substantive, are recorded as deferred revenue and recognized as revenue as the Company completes its performance obligations. A milestone event is considered substantive if (i) the milestone is commensurate with either (a) the Company s performance to achieve the milestone or (b) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company s performance to achieve the milestone; (ii) it relates solely to past performance and (iii) it is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. If any portion of the milestone payment does not relate to our performance, does not relate solely to past performance or is refundable or adjustable based on future performance, the milestone is not considered to be substantive. Milestone payments are not bifurcated into substantive and non-substantive components. Payments related to the achievement of non-substantive milestones is deferred and recognized over the Company s remaining performance period.

Royalty revenue will be recognized upon the sale of the related products provided the Company has no remaining performance obligations under the arrangement.

Research and development expenses

Research and development expenses are charged to expense as incurred. Research and development expenses comprise costs incurred in performing research and development activities, including personnel-related costs, stock-based compensation, facilities, research-related overhead, clinical trial costs, contracted services, manufacturing, license fees and other external costs. The Company accounts for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been consumed rather than when the payment is made.

Accrued research and development expenses

Clinical trial costs are recorded as a component of research and development expenses. The Company accrues and expenses clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with clinical research organizations and clinical trial sites. The Company determines the estimates through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including the Company s clinical development plan. The process of estimating clinical trial costs may become more complex as the Company s planned Phase 3 clinical trials will involve larger numbers of patients and clinical sites.

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The majority of the Company s service providers invoice the Company monthly in arrears for services performed or when contractual milestones are met. The Company makes estimates of the Company s accrued expenses as of each balance sheet date in the Company s financial statements based on facts and circumstances known to the Company at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Adjustments to prior period estimates have not been material for each of the years ended December 31, 2011 and 2012. Based on the amount of accrued research and development expenses as of December 31, 2012, it is the Company s assessment that deviations between the Company s estimated and actual amounts of 5% or less would not have a material impact on the Company s research and development expenses.

Examples of estimated accrued research and development expenses include:

- fees paid to clinical research organizations in connection with clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to vendors in connection with preclinical development activities;
- fees paid to vendors associated with the development of companion diagnostics; and
- fees paid to vendors related to product manufacturing, development and distribution of clinical supplies.

Nonrefundable advance payments for goods and services that will be used or rendered in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Stock-based compensation

The Company expenses the fair value of employee stock options over the vesting period. Compensation expense is measured using the fair value of the award at the grant date, net of estimated forfeitures, and is adjusted annually to reflect actual forfeitures. The fair value of each stock-based award is estimated using the Black-Scholes valuation model and is expensed using graded amortization over the vesting period.

Compensation expense for performance-based awards is estimated using the Black-Scholes valuation model and is expensed using the accelerated method. Compensation expense for performance-based awards reflects the estimated probability that the performance condition will be met.

The Company accounts for stock options granted to non-employees, which primarily consist of members of the Company s scientific advisory board and consultants, using the fair value approach. Stock options granted to non-employees are subject to revaluation each reporting period over their vesting terms.

Income taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted rates in effect for the year in which these temporary differences are expected to be recovered or settled. Valuation allowances are provided if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions and other issues. Reserves are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filing is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. Potential interest and penalties associated with such uncertain tax positions are recorded as components of income tax expense. To date, the Company has not taken any uncertain tax positions

or recorded any reserves, interest or penalties.

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Intangible assets

Intangible assets include patent rights and technology rights that have been acquired from third parties. They are reviewed for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives are no longer appropriate. The intangible assets are amortized on a straight-line basis over seven years.

Segment reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker, or CODM. The Company s Chief Executive Officer serves as its CODM. The Company views its operations and manages its business as one segment operating primarily in the United States. As of December 31, 2012, all of the Company s assets were located in the United States of America with the exception of $2.4 million of cash and cash equivalents and $0.3 million of other assets which were located in Canada. All of the Company s property and equipment was located within the United States as of December 31, 2012.

Fair value of financial instruments

The Company follows ASC 820-10, *Fair Value Measurements and Disclosures*, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1 Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2 Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument s anticipated life.

Level 3 Inputs reflect management s best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

Recent accounting pronouncements

In October 2009, FASB issued ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU 2009-13). This authoritative guidance provides principles for allocation of consideration among its multiple elements, allowing more flexibility in identifying and accounting for separate deliverables under an arrangement. ASU 2009-13 introduces an estimated selling price method for valuing the elements of a bundled arrangement if vendor-specific objective evidence or third-party evidence of selling price is not available, and significantly expands related disclosure requirements. This guidance is effective on a prospective basis for revenue arrangements entered into or materially modified in fiscals years beginning on or after June 15, 2010. Early adoption is permitted. The Company has adopted this guidance for the fiscal year beginning on January 1, 2010. The Company recognized revenue of $3 million during the year ended December 31, 2010 as a result of entering into an exclusive licensing arrangement with Kissei Pharmaceuticals (See Note 13). If the Company had recognized revenue from this arrangement under the guidance in effect prior to January 1, 2010, the up-front license payment may have been deferred and recognized over the estimated performance period under the arrangement as vendor-specific objective evidence or third-party evidence of selling price may not have been available for the undelivered items included in the licensing agreement, and therefore the undelivered items,

together with the license, may have been accounted for as a single unit of account. As ASU 2009-13 was adopted prior to entering into the agreement for which revenue was recognized in accordance with ASU 2009-13, adoption of the guidance does not impact comparability of any periods presented.

In April 2010, FASB issued ASU No. 2010-17, *Milestones Method of Revenue Recognition (Topic 605)* . This update provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. Authoritative guidance on the use of the milestone method did not previously exist. This guidance is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted. The Company has adopted this guidance for the fiscal year beginning on January 1, 2010. The Company s adoption of this guidance had no impact on its financial position, results of operations or cash flows for any period presented.

In May 2011, FASB issued ASU No. 2011-04, *Fair Value Measurement (Topic 82) Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards* (IFRSs) (ASU 2011-04). The amendments in this update will ensure that fair value has the same meaning in GAAP and in IFRS and that their respective fair value measurement and disclosure requirements are the same. ASU 2011-04 was effective for the Company in the first quarter of fiscal year 2012. The adoption of this standard has not had a material impact on the Company s financial position or results of operations.

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* (ASU 2011-05), which requires an entity to present total comprehensive income (loss), the components of net income (loss), and the components of other comprehensive income (loss) either in a single continuous statement of operations and comprehensive income (loss) or in two separate but consecutive statements. ASU 2011-05 does not change any of the components of comprehensive income (loss), but it eliminates the option to present the components of other comprehensive income (loss) as part of the statement of shareholders equity. ASU 2011-05 was effective for the Company in the first quarter of fiscal year 2012 and has been applied retrospectively. The adoption of this standard has not had a material impact on the Company s financial position or results of operations.

In April 2010, the FASB issued ASU No. 2010-13, *Compensation Stock Compensation (Topic 718): Effect of Denominating the Exercise Price of a Share-Based Payment Award in the Currency of the Market in which the Underlying Equity Security Trades.* ASC No. 718, *Compensation Stock Compensation,* provides guidance on whether share-based payments should be classified as either equity or a liability. Under this section, stock options which have a fixed price denominated in the functional currency of the respective Company s foreign operations or in the currency in which the employee is paid, does not result in the stock option being classified as a liability. The updated guidance clarifies that an employee share-based payment award, with an exercise price denominated in the currency of a market in which substantial portion of the entity s equity securities trade and which differs from the functional currency of the employer entity or payroll currency of the employee, is not considered to contain a condition that is not a market, performance or service condition. As such, these awards are classified as equity. ASU No. 2010-13 was effective for the Company in the first quarter of fiscal year 2011. The adoption of this standard has not had a material impact on the Company s financial position or results of operations.

In July 2013, the FASB issued ASU No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists* (ASU No. 2013-11), which concludes that, under most circumstances, an unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward. ASU No. 2013-11 will be effective for the Company beginning January 1, 2014. We do not anticipate that the adoption of this standard will have a material impact on our financial position or results of operations.

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3. Net loss per common share

Basic net loss per share is calculated by dividing the net loss attributable to common shareholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common shareholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, stock options and warrants are considered to be common share equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following table presents the computation of basic and diluted net loss per share (in thousands, except per share amounts):

	Years ended December 31,		Six months ended June 30,	
	2011	2012	2012 (unaudited)	2013 (unaudited)
Net loss per share:				
Net loss	$ (14,201)	$ (21,194)	$ (10,233)	$ (2,758)
Weighted-average common shares basic and diluted	2,345	3,045	2,956	3,150
Net loss per share basic and diluted per share	$ (6.05)	$ (6.94)	$ (3.46)	$ (0.88)

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of December 31, 2011 and 2012 and June 30, 2012 and 2013 as the Company recorded a net loss in all periods and, therefore, they would be anti-dilutive (in thousands):

	Years ended December 31,		Six months ended June 30,	
	2011	2012	2012 (unaudited)	2013 (unaudited)
Options to purchase common shares	191	241	163	301
Common share purchase warrants	679	919	919	919

4. Severance and exit costs

In April 2011, the Company relocated its core activities and headquarters from Vancouver, British Columbia to San Diego, California. In conjunction with this relocation the Company incurred a cash charge for cash severance and other termination benefits of approximately $1 million during the year ended December 31, 2011, which is included in operating expenses.

The Company rents a facility in Vancouver, British Columbia under a non-cancelable office service agreement. This office service agreement expires in December 2013. During June 2012 the Company vacated the Vancouver facility. As such the Company recorded $0.1 million in general and administrative expenses during the year ended December 31, 2012 which represented all of the future rent payments due under this office service agreement as the Company does not expect to receive any future economic value from this agreement.

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5. Intangible assets

The Company holds intangible assets that consist of patents and technology rights relating to the HUMxin and INxin platforms. Changes in the carrying value of intangible assets for the years ended December 31, 2011 and 2012 and the period ended June 30, 2013 (in thousands):

	December 31, 2011	2012	June 30, 2013 (unaudited)
Intangible asset	$ 1,372	$ 1,419	$
Less: accumulated amortization on intangible assets	(1,056)	(1,243)	
Less: write-off of remaining intangible assets		(176)	
Intangibles, net	$ 316	$	$

During the year ended December 31, 2012, the Company decided to focus its future development efforts solely on PRX302 for the treatment of BPH and has provided written notice to U.S. Public Health Services (PHS) of the Company s intention to terminate its license agreements with PHS which were being utilized to develop the Company s HUMxin and INxin technology platforms. Due to the change in the development focus and the termination of the license agreements the Company has determined there is no longer any economic value of the intangible assets associated with the HUMxin and INxin platforms. Accordingly, included in research and development expense for the year ended December 31, 2012 is a $0.2 million write-off associated with the impairment of these intangible assets.

Amortization expense for the Company s intangible assets was $0.2 million, and $0.1 million for the years ended December 31, 2011 and 2012, respectively.

6. Property and equipment

Property and equipment consisted of the following (in thousands):

	December 31, 2011	2012	June 30, 2013 (unaudited)
Equipment	$ 7	$ 7	$ 7
Computer hardware and software	34	42	44
Leasehold improvements	152	155	155
Furniture and fixtures	62	76	76
	255	280	282
Less: accumulated depreciation	(35)	(117)	(159)
	$ 220	$ 163	$ 123

Depreciation expense was $44 thousand and $82 thousand for the years ended December 31, 2011 and 2012, respectively. Depreciation expense was $40 thousand and $42 thousand for the six months ended June 30, 2012 and 2013, respectively.

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7. Accrued expenses

Accrued expenses as of December 31, 2011 and 2012 and June 30, 2013 consisted of the following (in thousands):

	December 31, 2011	December 31, 2012	June 30, 2013 (unaudited)
Accrued personnel related costs	$ 350	$ 753	$ 750
Accrued interest	119	93	71
Accrued research and development expenses	45	1,066	494
Other accrued expenses	71	927	714
	$ 585	$ 2,839	$ 2,029

8. Promissory notes

On July 15, 2011, the Company entered into a $15 million Loan and Security Agreement, as amended (the Oxford Loan) with Oxford Finance LLC (Oxford). Under the terms of the Oxford Loan, the Company made interest only payments for nine months at a fixed rate of 9.5%. Beginning in June 2012, the note began to amortize with principal and interest payments due through the remaining term of the loan. On July 31, 2013, the Company and Oxford entered into a second amendment to the Oxford Loan which authorized the Company to make an interest only payment on August 1, 2013 on the outstanding balance. The Company will resume making principal and interest payments on September 1, 2013 in accordance with the terms of the second amendment. The maturity date and the interest rate remain unchanged. In addition, no principal was extinguished in connection with the second amendment. The loan term, including interest only period, is 39 months; however, it can be prepaid subject to certain provisions and prepayment fees. Upon final repayment of the Oxford Loan on the maturity date, by prepayment, or upon acceleration of the Oxford Loan, the Company also must make an additional final payment of $0.8 million, which is being accreted over the term of the loan.

If the loan is prepaid, the following amounts are due: all outstanding principal plus all accrued interest and unpaid interest, the final payment of $0.8 million, a prepayment fee and any other sums due under the Oxford Loan, including certain of Oxford s expenses, as well as interest at the default rate for any past due amounts. The prepayment fee is set at two percent of the outstanding principal being prepaid if the loan is prepaid prior to July 2013 and one percent of the outstanding principal being prepaid if the loan is prepaid after July 2013.

In connection with the loan, the Company issued 26,971 warrants to purchase common shares up to July 15, 2018 at an exercise price of CND$26.88 per share. The fair value of this equity component was derived using the Black-Scholes valuation model and the fair value of the debt component which was derived based on an estimated effective interest discount rate had the debt been issued without an equity component. The $15.0 million proceeds were allocated to equity and the debt based on their respective fair values. The debt discount will be amortized to interest expense over the life of the debt. Interest on the term loan, consisting of the stated interest rate, final payment fee and amortization of the discount, is being recognized using the effective interest method.

The Company s Oxford Loan contains certain affirmative and negative covenants. One of the covenants included in the Oxford Loan required the Company to raise net cash proceeds from the sale and issuance of equity securities of no less than CND$7.5 million by March 31, 2012. The Company completed this issuance of additional equity securities during March 2012 as described in Note 11. The Company was in compliance with the covenants included in the Oxford Loan at December 31, 2011 and 2012 and June 30, 2013.

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To secure the Company s repayment obligations under the Oxford Loan, Oxford obtained a first priority security interest in all of the Company s assets, including intellectual property and all of the Company s equity interest in Sophiris Bio Corp. The roll forward of the secured promissory note is calculated as follows (in thousands):

Balance at January 1, 2011	$
Face value of issued secured promissory note	15,000
Fair value of equity	(519)
Accretion of debt discount	221
Balance at December 31, 2011	14,702
Accretion of debt discount	509
Principal paid	(3,190)
Balance at December 31, 2012	12,021
Accretion of debt discount (unaudited)	208
Principal paid (unaudited)	(2,878)
Balance at June 30, 2013 (unaudited)	$ 9,351

The Oxford loan has an interest rate of 9.50% per annum. The following table shows actual interest expensed and amortization of the debt discount that was charged to interest expense (in thousands):

	Years ended December 31,		Six months ended June 30,	
	2011	2012	2012 (unaudited)	2013 (unaudited)
Simple interest	$ 661	$ 1,325	$ 709	$ 482
Accretion of debt discount	221	509	264	208
Amortization of promissory notes issuance costs	69	155	80	61
	$ 951	$ 1,989	$ 1,053	$ 751

The following is a schedule of future maturities of the Company s debt as of December 31, 2012, including the final payment of $0.8 million due upon repayment of the loan (in thousands):

Years ending December 31,	Payments
2013	$ 5,895
2014	6,666
	$ 12,561

At December 31, 2011, the Company s promissory notes approximated their carrying amount due to the fact that there have been no significant changes in the Company s credit risk or in the interest rates from the funding of its promissory notes in July 2011.

The Company calculated the fair value of the secured promissory notes as $11.2 million (Level 3) as of December 31, 2012. The fair value of long-term debt is based on the net present value of calculated interest and principal payments, using an updated interest rate of 11% provided by the Company s lender which takes into consideration the financial position of the Company, the assessed credit rating of the Company by the

lender and the interest rate environment at December 31, 2012. As part of this fair value assessment the Company also confirmed with its lender an appropriate warrant coverage of 6% associated with the promissory notes. The fair value of this equity component was derived using the Black-Scholes valuation model. The Company calculated the promissory notes fair value by allocating to equity and the debt based on their respective fair values.

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The Company calculated the fair value of the secured promissory notes as $8.5 million (Level 3) as of June 30, 2013. The fair value of long-term debt is based on the net present value of calculated interest and principal payments, using an updated interest rate of 11% provided by the Company s lender which takes into consideration the financial position of the Company, the assessed credit rating of the Company by the lender and the interest rate environment at June 30, 2013. As part of this fair value assessment the Company also confirmed with its lender an appropriate warrant coverage of 6% associated with the promissory notes. The fair value of this equity component was derived using the Black-Scholes valuation model. The Company calculated the promissory notes fair value by allocating to equity and the debt based on their respective fair values.

9. Preferred shares

In 2003, the Company issued 34,444 shares of Series I Class A preferred shares, of which 31,985 shares were issued at $20.63 per share, less issuance costs of $6 thousand and 2,459 Series I Class A preferred shares were issued to settle accounts payable. Effective December 5, 2003, the preferred shares were split such that each holder of one share of preferred shares received 1.26 shares of preferred shares. All share numbers in these statements have been retroactively revised to reflect this change. In 2004, all 34,444 outstanding shares of Series I Class A preferred shares were converted into common shares.

As of December 31, 2011 and 2012 and June 30, 2013, the Company had unlimited shares of preferred shares authorized.

10. Shareholders equity

Authorized

As of December 31, 2011 and 2012 and June 30, 2013, the Company had unlimited shares of no par common shares authorized. There were 2.7 million, 3.1 million and 3.1 million common shares issued and outstanding as of December 31, 2011 and 2012 and June 30, 2013, respectively.

Warburg Pincus

On September 28, 2010, Sophiris entered into an investment agreement (the Investment Agreement) with Warburg Pincus Private Equity X, L.P. and Warburg Pincus X Partners, L.P. (together Warburg Pincus) whereby Warburg Pincus could invest up to CND$35 million, through a unit offering at CND$20.80 per unit, where each unit comprises one common share of Sophiris and 0.6 of a common share purchase warrant. Each whole warrant entitles the holder to purchase one common share of Sophiris at a price of CND$26.00, exercisable for a period of five years from the date of issue, subject to the acceleration of the expiration date in certain circumstances. The investment of the initial tranche of CND$10 million, closed in November 2010, the second tranche of CND$8.3 million, closed December 28, 2011 and the third tranche of CND$8.3 million, was closed March 28, 2012. In accordance with the terms of the Investment Agreement, Warburg Pincus ability to make future stock purchases under the Investment Agreement expired effective September 30, 2012 with Warburg Pincus making a total investment of CND$26.6 million of which $25.1 million is included as issuance of common shares from private placement, net of issuance cost, in the accompanying consolidated statement of cash flows. The Investment Agreement was terminated in July 2013, and the termination did not have a financial impact on the Company. The termination of the Investment Agreement had no effect on the outstanding common share purchase warrants held by Warburg Pincus.

Upon the closing of the initial investment under the investment agreement, the Company allocated the proceeds of CND$10 million, from the initial investment between the common shares and common share purchase warrants issued on November 19, 2010 and the remaining funds (right to invest) of CND$25 million, which could be issued in future periods under the Investment Agreement. The initial investment was allocated based upon the relative fair values of the common shares, common share purchase warrants and right to invest. The relative fair value was derived using the Black-Scholes method using the following assumptions: dividend

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yield of 0%; volatility of 79%; expected life of five years and risk-free interest rate of 2.4%. When the second and third tranches closed on December 31, 2011 and March 28, 2012, respectively, a portion of the fair value allocated to the right to invest was reclassified from right to invest to common shares. The second and third tranche relative fair values were derived using the Black-Scholes method using the following fair value assumptions: dividend yield of 0% and 0%; volatility of 72% and 65%; expected life of five years and five years, and a risk-free interest rates of 1.28% and 1.57%, respectively.

Private placement transactions

In March 2010, the Company completed a brokered private placement financing. The financing resulted in the issuance of 217,027 units at a price of CND$23.40 consisting of one common share and one-half common share purchase warrant (108,513 warrants issued) for net proceeds of $4.8 million.

During 2009, the Company closed a brokered private placement raising net proceeds of $1.8 million from the issuance of 164,500 common shares at CND$14.04 per common share. As part of the broker s commissions, the Company issued 9,686 broker warrants to purchase common shares at CND$14.04 per common share with an expiration date of May 20, 2011, which have been recorded as a cost of raising capital.

During 2008, the Company completed a brokered private placement financing. The financing consisted of the issuance of 134,510 common shares at a price of CND$36.40 resulting in net proceeds of $4.4 million.

During 2006, the Company completed a private placement financing. The financing consisted of two tranches of 352,875 units and 33,654 units at CND$26.00 per unit for net proceeds of $8.1 million. Each unit comprised one common share and one-half of one common share purchase warrant (193,264 warrants). As part of this transaction, the Company issued 3,846 shares as commissions on the private placement.

During 2005, the Company completed a non-brokered private placement which consisted of two tranches of 174,838 units and 51,000 units at CND$26.00 per unit for net proceeds of $4.7 million. Each unit comprised one common share and one common share purchase warrant (total of 225,839 warrants).

During 2004, the Company received net cash proceeds of $0.7 million from the issuance of 37,081 common shares.

During 2003, the Company issued 102,374 founder common shares at CND$0.000416 per share. The Company received net cash proceeds of $0.8 million from the issuance of 39,742 non-founder common shares at CND$26.00 per share, less issuance costs of $0.1 million. In addition, the Company issued 8,076 shares for $0.2 million.

During 2002, the Company issued 2 common shares for proceeds of CND$3 dollars.

Reverse acquisition

The consolidated financial statements of Sophiris (formally named Protox Therapeutics Inc.) reflect the reverse acquisition by Protox Pharmaceuticals, Inc. of SNB Capital Corp., a capital pool company under the policies of the TSX Venture Exchange Inc. The reverse acquisition by Protox Pharmaceuticals, Inc. of SNB Capital Corp. was approved by the shareholders of each company and was completed on July 9, 2004, at which time the Company was renamed Protox Therapeutics Inc.

Effective July 9, 2004, the Company issued 111,914 common shares on a one-for-one basis to the shareholders of Protox Pharmaceuticals Inc. to complete the acquisition of 100% of the issued and outstanding shares of Protox Pharmaceuticals Inc. Subsequent to the closing of the reverse acquisition, the former shareholders of Protox Pharmaceuticals Inc. controlled 69% of the issued and outstanding share capital of the Company immediately after the acquisition, constituting a reverse acquisition, with Protox Pharmaceuticals Inc. being the acquired company.

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As SNB Capital Corp. did not qualify as a business, the transaction was accounted for as an issuance of shares and options by Protox Pharmaceuticals Inc. for the net monetary assets of SNB Capital Corp., accompanied by a recapitalization of the Company.

Initial Public Offering on Toronto Stock Exchange

During 2004, the Company completed an initial public offering on the Toronto Stock Exchange to list its shares on the Toronto Stock Exchange consisting of 86,116 units at CND$52.00, per unit (each unit consisting of one common share of the Company and one half of one common share purchase warrant, or 43,058 warrants) to net the Company CND$3.8 million, after commissions and other offering costs. The proceeds from this offering were allocated based upon the relative fair values of the common shares and the warrants. The fair value of the warrants was determined using the Black-Scholes valuation model.

Shares reserved for future issuance

The shares reserved for future issuance as of December 31, 2011 and 2012 and June 30, 2013 consisted of the following (in thousands):

	December 31,		June 30,
	2011	2012	2013 (unaudited)
Common share purchase warrants	679	919	919
Stock options			
Granted and outstanding	191	241	301
Reserved for future issuance	32	74	14
	901	1,234	1,234

11. Common share purchase warrants

On March 28, 2012, the Company closed a third tranche of CND$8.3 million under its Investment Agreement with Warburg Pincus. In conjunction with the closing the Company issued 400,635 units comprising one common share and 0.6 of a common share purchase warrant. Each whole warrant entitles the holder to purchase one common share at a price of CND$26.00. The warrant will expire five years after the date of grant. The expiration date of the warrant can accelerate in certain circumstances.

The common share purchase warrant activity is as follows (in thousands, except exercise price data):

	Number outstanding	Weighted average exercise price CND$
Balance outstanding January 1, 2011	416	$ 28.08
Exercised warrants	(5)	14.04
Issuance of warrants with promissory notes	27	27.04
Issued with private placement shares	241	26.00
Warrants expired		
Balance outstanding December 31, 2011	679	27.56
Issued with private placement shares	240	26.00
Balance outstanding December 31, 2012	919	27.04
No changes		

Balance outstanding	June 30, 2013 (unaudited)	919	27.04

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The following table summarizes the expiration dates for the Company s outstanding common share purchase warrants as of June 30, 2013 (in thousands):

Number of warrants outstanding	Expiration date
289	November 19, 2015
123	March 16, 2015
27	July 15, 2018
240	December 28, 2016
240	March 28, 2017
919	

12. Stock-based compensation plan

The Company s stock option plan (the Plan) provides for the granting of options for the purchase of common shares of the Company at the fair market value of the Company s common shares on the date of the option grant. Options are granted to employees, directors and non-employees. The board of directors or a committee appointed by the board of directors administers the Plan and has discretion as to the number, vesting period and expiry date of each option award. The Company grants options to residents of the United States with an exercise price denominated in Canadian dollars, the functional currency of Sophiris Bio Inc. In accordance with ASU No. 2010-13 *Compensation Stock Compensation (Topic 718): Effect of Denominating the Exercise Price of a Share-Based Payment Award in the Currency of the Market in which the Underlying Equity Security Trades a consensus of the FASB Emerging Issues Talk Force*, these options are classified as equity as the Canadian dollar is the currency in which a substantial portion of the entity s equity securities trade.

The Plan is based on a cumulative percentage of options issuable up to 10% of the Company s outstanding common shares. As of December 31, 2011 and 2012 and June 30, 2013, there were 32,624, 74,000 and 14,376 shares, respectively, available to be issued under the Plan.

During 2011 and 2012 and the six months ended June 30, 2013, the Company issued options to purchase 79,326, 102,044 and 42,864 common shares, respectively, to its directors and employees. These options generally vest over a three year period for employees and over a one year period for directors. The maximum contractual period for the granted options is five years.

No options to purchase common shares were granted to non-employees during the years ended December 31, 2011 and 2012. During the six months ended June 30, 2013 the Company issued options to purchase 28,346 common shares to non-employees. In connection with options granted to non-employees, we recognized expense of $49,754, $20,944 and $76,094 for the years ended December 31, 2011 and 2012 and the six months ended June 30, 2013, respectively. The Company accounts for stock options granted to non-employees using the fair value approach. Stock options granted to non-employees are subject to revaluation at each reporting period over their vesting terms.

The Company recognized stock-based compensation expense as follows (in thousands):

	Years ended December 31,		Six months ended June 30,	
	2011	2012	2012 (unaudited)	2013 (unaudited)
Research and development	$ 317	$ 148	$ 91	$ 124
General and administrative	598	528	253	401
	$ 915	$ 676	$ 344	$ 525

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As of December 31, 2011 and 2012 and June 30, 2013, there was $683,000, $764,000 and $750,000, respectively, of total unrecognized compensation costs related to non-vested stock awards. As of December 31, 2011 and 2012 and June 30, 2013, the Company expects to recognize those costs over weighted average periods of approximately 1.6 years, 1.5 years and 1.5 years, respectively.

The fair value of options granted during the year ended 2011 and 2012, and the six months ended June 30, 2013 were estimated at the date of grant using the following weighted-average assumptions:

	Years ended December 31,		Six months ended June 30,	
	2011	2012	2012 (unaudited)	2013 (unaudited)
Expected Life of the Option Term (years)	4.5	3.9	4.0	4.2
Risk-free interest rate	1.93%	1.24%	1.44%	1.38%
Dividend rate	0%	0%	0%	0%
Volatility	74.8%	73.9%	75.5%	69.1%
Forfeiture rate	8.7%	9.0%	7.8%	8.8%
Estimated weighted-average fair value per stock option (CND$)	$ 16.12	$ 8.84	$ 13.52	$ 7.80

Expected Life of the Option Term This is the period of time that the options granted are expected to remain unexercised. Options granted have a maximum contractual term of five years. The Company estimates the expected life of the option term based on actual past behavior for similar options.

Risk-Free Interest Rate This is the Canadian Treasury rate for the week of each option grant during the quarter having a term that most closely resembles the expected life of the option.

Dividend Rate The Company has never declared or paid dividends on common shares and has no plans to do so in the foreseeable future.

Volatility Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated or is expected to fluctuate during a period. The Company considered the historical volatility from its IPO through the dates of grants.

Forfeiture Rate Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company assesses the forfeiture rate on an annual basis and revises the rate when deemed necessary.

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The following table summarizes stock option activity, including options issued to employees, directors and non-employees (in thousands, except per share and contractual term data):

	Options outstanding	Weighted average exercise price in CND$	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at January 1, 2011	137	$ 32.24	2.9	$ 844
Options granted	79	27.04		
Options expired	(1)	27.04		
Options exercised	(11)	27.04		
Options forfeited	(13)	32.28		
Outstanding at December 31, 2011	191	$ 30.16	3.2	$
Options granted	102	16.12		
Options expired	(29)	37.44		
Options forfeited	(23)	25.48		
Outstanding at December 31, 2012	241	$ 23.92	3.5	$
Options granted (unaudited)	71	13.00		
Options expired (unaudited)	(10)	44.72		
Options forfeited (unaudited)	(1)	35.36		
Outstanding at June 30, 2013 (unaudited)	301	$ 20.80	3.5	106
Vested or expected to vest at June 30, 2013 (unaudited)	280	$ 20.98	3.4	$ 93
Exercisable at June 30, 2013 (unaudited)	111	$ 29.12	2.1	$

The aggregate intrinsic value was calculated as the difference between the exercise price of the stock options and the fair value of the underlying common shares as of the respective balance sheet date. The aggregate intrinsic value of options exercised during the year ended December 31, 2011 was $0. No stock options were exercised during the year ended December 31, 2012 or the six months ended June 30, 2013.

The Company settles employee stock option exercises with newly issued common shares.

Cash received from the 10,827 common shares issued upon option exercises during the year ended December 31, 2011 was $0.3 million. The Company did not recognize any income tax benefit from stock option exercises as the Company continues to record a valuation allowance on its deferred tax assets.

13. License agreements

Kissei Agreement

In April 2010, the Company entered into an exclusive license agreement for the development and commercialization of PRX302 (and other products covered by the licensed patent). The agreement with Kissei Pharmaceuticals Co., Ltd., a Japanese pharmaceutical company, (Kissei) covers the development and commercialization of PRX302 in Japan for the treatment of the symptoms of BPH, prostate cancer, prostatitis or other diseases of the prostate. Pursuant to the agreement in 2010, the Company received an upfront license payment of $3.0 million.

The Company has determined that the deliverables under this agreement included the license, the transfer of relevant technical information and participation in a periodic development meeting. The Company recognized the entire upfront license payment upon receipt as the license was deemed to have stand-alone value and no significant undelivered performance obligations were identified in connection with the license.

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The agreement also notes that the Company shall supply Kissei with bulk material under a separate supply agreement for use in future clinical studies and, if approved, for commercial sales. The license agreement also notes that if the Company is unwilling or unable to supply Kissei with the necessary bulk material that Kissei will have the option to manufacture the bulk material themselves or they can outsource the manufacturing to a third party. To date the Company and Kissei have not signed a supply agreement.

The agreement also provides that the Company shall have full responsibility, including financial responsibility, for filing, prosecuting and maintaining all of the patents in Japan during the term of the agreement. The filing of patents is an administrative and perfunctory deliverable. The associated costs are immaterial. The prosecution and maintenance of patents is not considered an undelivered performance obligation.

During the six months ended June 30, 2013, the Company recorded as revenue a $5.0 million non-refundable substantive milestone payment due from Kissei upon the achievement of certain development activities during the six months ended June 30, 2013, as such milestone had been achieved during this period. In accordance with the Company s revenue recognition policy, the Company recognizes the receipt of milestone payments in accordance with the milestone method in the period in which the underlying triggering event occurs. The Company received payment for the milestone in April 2013.

In addition to the upfront license payment and the $5.0 million milestone payment recognized as revenue during the six months ended June 30, 2013, the Company is entitled to receive up to $67.0 million of non-refundable milestone payments as follows: a total of $12.0 million for 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 for the prostate cancer indication, of which $7.0 million relates to the completion of certain 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 for prostatitis or other diseases of the prostate, of which $7.0 million relates to the completion of certain 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.

Management evaluated the nature of the events triggering these additional milestone payments, and concluded that these events fall into two categories: (a) events which involve the performance of the Company s obligations under the Kissei license agreement, and (b) events which do not involve the performance of the Company s obligations under the Kissei license agreement.

Milestone payments which involve the performance of the Company s obligations include activities related to the completion of development activities and regulatory approvals in the United States. Management concluded that each of these payments constitutes a substantive milestone. This conclusion was based primarily on the facts that (i) each triggering event represents a specific outcome that can be achieved only through successful performance by the Company of one or more of its deliverables, (ii) achievement of each triggering event was subject to inherent risk and was not reasonably assured at the inception of the agreement, (iii) each of these milestones is non-refundable, (iv) substantial effort is required to complete each milestone, (v) the amount of each milestone payment is reasonable in relation to the value created in achieving the milestone, (vi) a substantial amount of time is expected to pass between the up-front payment and the potential milestone payments, and (vii) the milestone payments relate solely to past performance. Based on the foregoing, the Company recognizes any revenue from these milestone payments under the milestone method in the period in which the underlying triggering event occurs.

Milestone payments which do not involve the performance of the Company s obligations include the completion of development activities, regulatory approvals and certain product sale goals in Japan, all of which are areas in which the Company has no pertinent contractual responsibilities under the agreement. Management

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concluded that these milestones are not substantive and will be recognized in accordance with the Company s accounting policy for revenue recognition.

The following table breaks down the remaining unpaid milestone payments by indication or, in the case of milestones not associated with a specific indication, by triggering events and by involvement of the Company:

	Milestone Payments Involving Performance of Company Obligations	Milestone Payments Not Involving Performance of Company Obligations
Milestones by Indication		
BPH		$ 12 million
Prostate cancer		$ 21 million
Prostatitis and other diseases of the prostate		$ 21 million
Milestones Not Associated with an Indication		
Gross sale targets		$ 8 million
Regulatory approvals	$ 5 million	

The Company may also receive a drug supply fee, assuming the Company supplies material to Kissei, and royalty payments in the 20-29% range as a percentage of future net sales of licensed products sold under the agreement.

Kissei is not currently studying PRX302 for the treatment of prostate cancer, prostatitis or other diseases of the prostate. In addition, Kissei has the option to sublicense the development and commercialization for PRX302 in their territory.

PRX302 license agreement for Benign Prostate Hyperplasia

In 2009, the Company signed an exclusive license agreement with UVIC Industry Partnerships Inc. and The John Hopkins University with respect to the use of PRX302 for the treatment of the symptoms of benign prostate hyperplasia and other non-cancer diseases and conditions of the prostate. The license agreement requires the Company to make payments of CND$1.3 million in the aggregate on the achievement of certain clinical and regulatory milestones and to pay royalties on commercial sales of resulting products. To the extent the Company receives any milestone payments relating to the development of therapeutics for the treatment of the symptoms of BPH under its exclusive license agreement with Kissei, the Company is obligated to pay a percentage of such consideration, which percentage is in the 10-19% range, to UVIC and Johns Hopkins.

During the six months ended June 30, 2013, the Company expensed a $0.1 million milestone payment due under the agreement upon the completion of the Company s last Phase 2b clinical trial prior to commencing a Phase 3 clinical trial. The Company anticipates paying this milestone upon the enrollment of the Company s first patient in a Phase 3 clinical trial for the treatment of the symptoms of BPH. The Company anticipates initiating its Phase 3 clinical trial in the second half of 2013. This amount was expensed to research and development expense. In addition, the Company accrued a sub-license royalty of $0.4 million payable under the agreement associated with the Company s $5.0 million milestone payment from Kissei. The Company paid this amount during April 2013. This amount was recorded as a component of research and development expense.

From the inception of the agreement, the Company has incurred sub-license fees of $0.6 million and milestone payments of $0.1 million under this agreement.

INxin technology license and acquisition

Pursuant to an exclusive license agreement with the U.S. Public Health Service (PHS), the Company had agreed to make cumulative milestone payments of up to $4.0 million contingent upon the achievement of certain clinical and regulatory milestones and to pay royalties on commercial sales of resulting products. As the Company has decided to focus its development efforts solely on PRX302 it has filed to terminate the INxin

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license agreement with PHS. Through December 31, 2012, the Company has paid milestone payments of $30 thousand and in conjunction with the termination of the license agreement the Company does not expect to make any future milestone payments.

HUMxin technology license agreement

Pursuant to an exclusive license agreement with PHS, the Company had agreed to make cumulative milestone payments of up to $4.8 million contingent upon the achievement of certain clinical and regulatory milestones and to pay royalties on commercial sales of resulting products. As the Company has decided to focus its development efforts solely on PRX302 it has filed to terminate the HUMxin license agreement with PHS. Through December 31, 2012, the Company has paid milestone payments of $30 thousand and in conjunction with the termination of the license agreement the Company does not expect to make any future milestone payments.

14. Income taxes

The $5.0 million milestone payment from Kissei was subject to a 10% Japanese withholding tax. As a result, the Company recorded income tax expense of $0.5 million for the six months ended June 30, 2013. The Company will be eligible to utilize the withholding tax to offset future taxes due in Japan. Given the uncertainty around the Company s ability to generate future taxable income, the Company has expensed the withholding tax during the six months ended June 30, 2013.

The component of the loss before provision for income taxes were as follows (in thousands):

	Years ended December 31,	
	2011	2012
United States	$ (108)	$ (1,184)
Canada	(14,093)	(20,009)
	$ (14,201)	$ (21,193)

The components of the provision for income taxes from continuing operations is as follows (in thousands):

	Years ended December 31,	
	2011	2012
Current Tax:		
Canada	$	$
US		
State		
	$	$
Deferred Tax:		
Canada	$	$
US		
State		
	$	$

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A reconciliation on income taxes to the amount computed by applying the statutory federal income tax rate to the net loss is as follows (in thousands, except income tax rates):

	Years ended December 31,	
	2011	2012
Combined federal and provincial income tax rates	26.5%	25%
Income tax benefit at statutory rates	$ (3,763)	$ (5,299)
State income tax, net of federal benefit		(46)
Permanent items	30	80
Tax credits	(134)	(81)
Non-deductible stock-based compensation	281	132
Rate differential	(12)	(107)
Other	140	(36)
Change in valuation allowance	3,458	5,357
Income tax expense	$	$

Significant components of the Company s deferred tax assets as of December 31, 2011 and 2012 are shown below (in thousands):

	December 31,	
	2011	2012
Deferred tax assets:		
Net operating loss carryforwards (non-capital losses)	$ 10,461	$ 15,618
Scientific research and development	2,515	2,574
Tax credits	2,517	2,655
Stock based compensation		241
Other, net	658	920
Share issue costs	302	198
Total deferred tax assets, net, before valuation allowance	16,453	22,206
Valuation allowance	(16,453)	(22,206)
Net deferred tax assets	$	$

Due to the operating losses since inception, a valuation allowance has been recognized to offset net deferred assets as realization of such deferred tax assets is not more likely than not. During the years ended December 31, 2011 and 2012, the valuation allowance on the deferred tax assets increased by $3.2 million and $5.8 million, respectively.

At December 31, 2012, the Company has tax losses for income tax purposes in Canada and in the United States which may be used to reduce taxable income. The income tax benefit, if any, of these losses has not been recorded due to the uncertainty of its recovery. Based upon statute, losses are expected to expire as follows (in thousands):

Expiration date	Canada	U.S. Federal	Total
2013	$ 501	$	$ 501
2014	1,343		1,343
2015	3,642		3,642
2026	3,616		3,616
2027	5,342		5,342

2028	6,079		6,079
2029	4,844		4,844
2030	4,399		4,399
2031	13,052	3	13,055
2032	19,590	36	19,626
	$ 62,408	$ 39	$ 62,447

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In addition, the Company has $51 thousand of U.S. state net operating loss carryforwards which begin to expire in 2032.

At December 31, 2012, the Company had investment tax credits in Canada and the United States that expire as follows (in thousands).

Expiration date	Canada	U.S. Federal	Total
2015	$ 33	$	$ 33
2016	84		84
2017	149		149
2018	213		213
2019	207		207
2020	43		43
2021	10		10
2023	36		36
2024	119		119
2025	252		252
2026	244		244
2027	380		380
2028	477		477
2029	603		603
2030	188		188
2031	28	68	96
	$ 3,066	$ 68	$ 3,134

In addition, the Company has $0.2 million of United States research and development credits which carry forward indefinitely.

The Company s Canadian tax years are subject to inspection from 2007 forward. The Company s United States Federal and California 2011 tax returns are subject to examination by taxing authorities.

The future utilization of the Company s research and development credit carry forwards and net operating loss carry forwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that may have occurred previously or may occur in the future. The Tax Reform Act of 1986 (the Act) limits a company s ability to utilize certain tax credit carry forwards and net operating loss carry forwards in the event of a cumulative change in ownerships in excess of 50% as defined in the Act.

The Company recognizes interest and/or penalties related to income tax matters in income tax expense. For the years ended December 31, 2011 and 2012, we have not recognized any interest or penalties related to income taxes.

In 2011, the Company adopted the recognition and measurement principals under ASC740, *Income Taxes* (ASC740) regarding the recognition of tax benefits. In accordance with ASC740, tax benefits are only recognized when a position is more likely than not of being sustained. Tax benefits are then measured using a cumulative benefit approach whereby the largest amount of tax benefit that is more likely than not of being sustained is recognized. The Company has no unrecognized benefits recorded as of December 31, 2011 and 2012.

The American Taxpayer Relief Act of 2012 was enacted into law on January 2, 2013. The change in tax law, which reinstated the United States federal research and development tax credit retroactively from January 1, 2012 through December 31, 2013, will be reflected in the computation of our estimated annual effective tax rate beginning in the first quarter of 2013. The retroactive impact related to 2012 will be treated as a discrete tax item during the first quarter of 2013.

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15. Commitments and contingencies

Operating leases

The Company leases a facility, comprising the Company s headquarters, located in San Diego, California under a non-cancelable lease. This lease expires in May 2014 and the rent is $12,741 per month.

The Company rents a second facility in Vancouver, British Columbia under a non-cancelable office service agreement. This office service agreement expires in December 2013 and the rent is CND$3,744 per month, or $3,588 per month, as converted, subject to annual cost of living increases. During June 2012 the Company vacated the Vancouver facility. As such the Company recorded $0.1 million of expense during the year ended December 31, 2012 which represented all of the future rent payments due under this lease as the Company does not expect to receive any future economic value from this agreement.

Total rent expense under these operating leases was $0.1 million and $0.2 million for the years ended December 31, 2011 and 2012, respectively and $0.2 million and $0.1 million for the six months ended June 30, 2012 and 2013, respectively. As noted above, included as a component of the rent expense for the year ended December 31, 2012 is $0.1 million of future rent payments due on the Vancouver facility.

Future minimum lease payments under non-cancelable operating leases at June 30, 2013 are as follows (in thousands):

	Future rent payments
2013	$ 111
2014	72
Total	$ 183

License agreements

The Company has license agreements with third parties that require the Company to make annual license maintenance payments and contingent future payments upon the success of licensed products that include milestone and/or royalties. Minimum future payments over the next five years are not material.

Purchase commitments

The Company is required to schedule its manufacturing activities in advance. If the Company cancels any of these scheduled activities without proper notice the Company would be required to pay penalties equal to the cost of the originally scheduled activity. The Company estimates that the cost of these penalties would be approximately $1.5 million at June 30, 2013 if the Company s scheduled activities are cancelled.

16. Subsequent events

For its financial statements as of December 31, 2012 and for the year then ended, the Company evaluated subsequent events through February 14, 2013, the date on which those financial statements were originally available to be issued. The Company has also evaluated subsequent events through August 12, 2013 for the effects of the share consolidation described in Note 1.

17. Subsequent events (unaudited)

For its interim financial statements as of June 30, 2013 and for the six months then ended, the Company evaluated subsequent events through August 7, 2013, the date on which those financial statements were originally available to be issued, and through August 12, 2013, the date on which these financial statements were available to be reissued.

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13,000,000 Shares

Common Shares

PROSPECTUS

August 16, 2013

Citigroup

Leerink Swann

Stifel

Lazard Capital Markets

Until September 10, 2013 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common shares, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.