

SOPHIRIS BIO INC.

Form 424B3

January 26, 2015

Filed Pursuant to Rule 424(b)(3)

Registration No. 333-196331

Prospectus Supplement No. 3

(to prospectus dated June 23, 2014)

Sophiris Bio Inc.

This Prospectus Supplement No. 3 supplements and amends the prospectus dated June 23, 2014, or the Original Prospectus, and Prospectus Supplement No. 2 thereto, dated July 7, 2014 and Prospectus Supplement No. 3 thereto, dated August 7, 2014, which we refer collectively to as the Prospectus, relating to the sale of an aggregate of 3,409,629 of our common shares, no par value, by the selling shareholder identified in the Original Prospectus.

On November 12, 2014, we filed with the Securities and Exchange Commission a Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014. The information set forth below supplements and amends the information contained in the Prospectus. This Prospectus Supplement No. 3 should be read in conjunction with, and delivered with, the Prospectus and is qualified by reference to the Prospectus except to the extent that the information in this Prospectus Supplement No. 3 supersedes the information contained in the Prospectus.

The prices at which the selling shareholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the selling shareholder. However, we may receive proceeds of up to \$15.0 million from the sale of our common shares to the selling shareholder, pursuant to a common stock purchase agreement entered into with the selling shareholder on May 16, 2014, including proceeds that we have already received thereunder.

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

Our common shares trade on the NASDAQ Global Market, or NASDAQ, under the ticker symbol “SPHS”. On January 23, 2015, the last reported sale price per common share was \$0.46 per share.

This investment involves risks. See “Risk Factors” on page 7 of the Original Prospectus.

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

The date of this Prospectus Supplement No. 3 is January 26, 2015.

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
ACT OF 1934**

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2014

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
ACT OF 1934**

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission file number: 001-36054

Sophiris Bio Inc.

(Exact name of registrant as specified in its charter)

British Columbia

(State or Other Jurisdiction of Incorporation or Organization)

98-1008712

(I.R.S. Employer Identification No.)

1258 Prospect Street, La Jolla, California
(Address of Principal Executive Offices)

92037
(Zip Code)

858-777-1760

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 12, 2014, the registrant had 16,844,736 shares of Common Stock (no par value) outstanding.

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SOPHIRIS BIO INC.

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Table Of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****Sophiris Bio Inc.****Condensed Consolidated Balance Sheets****(In thousands, except share amounts)****(Unaudited)**

	September 30, 2014	December 31, 2013
Assets:		
Current assets:		
Cash and cash equivalents	\$ 16,174	\$ 14,839
Securities available-for-sale	12,970	33,310
Other receivables	18	48
Prepaid expenses	3,101	3,598
Total current assets	32,263	51,795
Property and equipment, net	40	78
Other long-term assets	19	19
Total assets	\$ 32,322	\$ 51,892
Liabilities and shareholders' equity:		
Current liabilities:		
Accounts payable	\$ 3,871	\$ 1,470
Accrued expenses	2,912	2,181
Current portion of promissory notes	154	6,877
Total current liabilities	6,937	10,528
Long-term promissory notes	5,754	-
Warrant liability	-	883
Stock-based compensation liability	129	202
Total liabilities	12,820	11,613
Commitments and contingencies		
Shareholders' equity:		
Common shares, unlimited authorized shares, no par value; 16,844,736 and 16,149,871 shares issued and outstanding at September 30, 2014 and December 31, 2013	113,089	111,204
Contributed surplus	16,592	13,824
Accumulated other comprehensive gain	101	98
Accumulated deficit	(110,280)	(84,847)

Total shareholders' equity	19,502	40,279
Total liabilities and shareholders' equity	\$ 32,322	\$ 51,892

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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Table Of Contents**Sophiris Bio Inc.****Condensed Consolidated Statements of Operations and Comprehensive Loss****(In thousands, except per share amounts)****(Unaudited)**

	Three Months Ended September 30, 2014		Nine Months Ended September 30, 2013	
Revenues:				
License revenue	\$—	\$—	\$—	\$5,000
Operating expenses:				
Research and development	6,710	2,117	20,629	6,143
General and administrative	1,370	883	4,316	3,009
Total operating expenses	8,080	3,000	24,945	9,152
Other income (expense):				
Interest expense	(175)	(313)	(551)	(1,064)
Interest income	10	—	40	—
Gain on revaluation of warrant liability	—	195	49	195
Other income (expense), net	21	166	(27)	(190)
Total other income (expense)	(144)	48	(489)	(1,059)
Net loss before income taxes	(8,224)	(2,952)	(25,434)	(5,211)
Income tax expense	—	—	—	(500)
Net loss	\$(8,224)	\$(2,952)	\$(25,434)	\$(5,711)
Basic and diluted loss per share	\$(0.49)	\$(0.31)	\$(1.54)	\$(1.08)
Weighted average number of outstanding shares – basic and diluted	16,845	9,509	16,499	5,293
Other comprehensive income (loss):				
Foreign currency translation adjustment	—	(154)	—	146
Unrealized (loss) gain on securities available-for-sale	(1)	—	3	—
Total other comprehensive loss	\$(8,225)	\$(3,106)	\$(25,431)	\$(5,565)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Table Of Contents**Sophiris Bio Inc.****Condensed Consolidated Statements of Cash Flows****(In thousands)****(Unaudited)**

	Nine Months Ended September 30,	
	2014	2013
Cash flows used in operating activities		
Net loss for the period	\$(25,434)	\$(5,711)
Adjustments to reconcile net loss to net cash used by operating activities:		
Stock-based compensation	1,738	715
Amortization of debt discount	155	299
Depreciation of property and equipment	42	63
Amortization of promissory note issuance costs	38	86
Amortization of discount on securities available-for-sale	34	—
Change in fair value warrant liability	(49)	(195)
Foreign exchange transaction (gain) loss	(14)	216
Other	3	—
Changes in operating assets and liabilities:		
Other receivables	30	36
Prepaid expenses	458	(2,680)
Other long-term assets	—	6
Accounts payable	2,422	(174)
Accrued expenses	783	(1,483)
Net cash used in operating activities	(19,794)	(8,822)
Cash flows provided by (used in) investing activities		
Purchases of property and equipment	(7)	(3)
Maturities of securities available-for-sale	38,301	—
Purchases of securities available-for-sale	(17,992)	—
Net cash provided by (used in) investing activities	20,302	(3)
Cash flows provided by (used in) financing activities		
Issuance of common shares from private placement, net of issuance cost	1,891	—
Issuance of common shares from public offering, net of issuance cost	—	57,816
Payment of issuance costs in connection with public offering	(53)	—
Cash received from the issuance of promissory notes	2,362	—
Principal payments on promissory notes	(3,361)	(3,903)
Net cash provided by financing activities	839	53,913
Effect of exchange rate changes on cash and cash equivalents	(12)	(70)
Net increase in cash and cash equivalents	1,335	45,018
Cash and cash equivalents at beginning of period	14,839	9,721

Cash and cash equivalents at end of period	\$16,174	\$54,739
Supplemental disclosures of non-cash investing and financing activities:		
Reclassification of fair value of warrant liability to equity as a result of the amendment of the underlying common share purchase warrants	\$834	\$—
Value of warrants issued in connection with promissory notes	\$124	\$—
Change in the fair value of stock-based compensation liability recorded to contributed surplus	\$73	\$—

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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Sophiris Bio Inc.

Notes to the Condensed Consolidated Financial Statements

(Unaudited)

1. Nature of the business

Company

Sophiris Bio Inc., or the Company, or Sophiris, is a clinical-stage biopharmaceutical company currently developing PRX302 for treatment of the symptoms of benign prostatic hyperplasia, or BPH, commonly referred to as an enlarged prostate and for the treatment of localized low to intermediate risk prostate cancer. The Company is governed by the British Columbia Business Corporations Act and began operations on January 11, 2002. The Company's operations were initially located in Vancouver, British Columbia until April 2011, when its core activities and headquarters relocated from Vancouver, British Columbia to San Diego, California.

2. Recently adopted accounting pronouncements

On June 10, 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-10, "*Development Stage Entities (Topic 915) – Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation,*" which eliminates the concept of a development stage entity in its entirety from current accounting guidance and provides for certain amendments to the consolidation guidance in Topic 810 in the Accounting Standards Codification, or ASC. Prior to the issuance of this guidance the Company was considered a development stage entity and as a result the Company included certain inception-to-date disclosures in its financial statements. The guidance related to the elimination of the concept of a development stage entity is effective for public companies for annual reporting periods beginning after December 15, 2014, and interim periods therein. The amendment of the consolidation guidance in Topic 810 is effective for public companies for annual reporting periods beginning after December 15, 2015. Early adoption of the new standard was permitted. ASU No. 2014-10 was adopted by the Company during the quarter ended June 30, 2014. As such all inception-to-date disclosures have been removed from these condensed consolidated financial statements.

3. Summary of significant accounting policies

Significant accounting policies followed by the Company in the preparation of its condensed consolidated financial statements are as follows:

Basis of consolidation

The condensed 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 unaudited condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States, or GAAP, for the interim financial information and the rules and regulations of the Securities and Exchange Commission, or SEC, related to quarterly reports on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by GAAP for annual audited financial statements and should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K, or Annual Report, filed with the SEC. The year-end condensed balance sheet data was derived from the audited consolidated financial statements, but does not include all disclosures required by GAAP. In the opinion of management, these condensed consolidated financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair statement of the financial position, results of operations and cash flows for the periods presented. The results of operations for the interim periods shown in this report are not necessarily indicative of the results that may be expected for any future period, including the full year.

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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 condensed consolidated financial statements include revenue recognition, stock-based compensation expense, warrant liability, 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. 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.

Foreign currency

Gains and losses resulting from foreign currency translation are recorded in accumulated other comprehensive gain (loss), which is a separate component of stockholders' equity. Foreign currency transaction gains and losses are recognized as a component of other income (expense), net. The Company recorded foreign exchange transaction gains and (losses) of \$21,000 and (\$24,000) for the three months and nine months ended September 30, 2014, respectively, and \$166,000 and (\$223,000) for the three and nine months ended September 30, 2013, respectively.

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.

Securities Available-for-Sale

Investments with an original maturity of more than three months when purchased have been classified by management as securities available-for-sale. Such investments are carried at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive gain (loss) in shareholders' equity. Realized gains and losses on available-for-sale securities are included in interest income. No other-than-temporary impairments were identified for the investment securities held by the Company as of September 30, 2014 or December 31, 2013. The cost of investment securities classified as available-for-sale is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. The cost of securities sold is

based on the specific-identification method. The Company has classified all of its investment securities as available-for-sale, including those with maturities beyond one year, as current assets on the consolidated balance sheets based on the highly liquid nature of the investment securities and because these investment securities are considered available for use in current operations.

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.

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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 nor third-party evidence exists, the 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 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 the Company's 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 costs 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 of the total work 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 based on facts and circumstances known to the Company as of each balance sheet date. 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 ongoing and planned Phase 3 clinical trials involve larger numbers of patients and clinical sites.

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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.

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 recorded as a prepaid expense 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 pricing model and is expensed using graded amortization over the vesting period.

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.

Prior to the Company's initial public offering, or IPO, the Company had issued its stock options with a Canadian dollar denominated exercise price. Subsequent to the Company's IPO, the Company issues its stock options with a U.S. dollar denominated exercise price.

Effective November 13, 2013, the Company voluntarily delisted from the Toronto Stock Exchange, or TSX. As a result of the delisting from the TSX and the change in the Company's functional currency to the U.S. dollar, the stock options granted with exercise prices denominated in Canadian dollars are considered dual indexed as defined in ASC 718, "*Compensation, Stock Compensation*". As a result, the Company is required to account for these stock options as a liability. Historically these options had been accounted for as equity. The estimated fair value is determined using the Black-Scholes pricing model based on the estimated value of the underlying common shares at the valuation measurement date, the remaining service period of the stock options, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common shares. The fair value of the stock-based compensation liability was \$129,000 at September 30, 2014. As the calculated fair value of the stock options at September 30, 2014 was less than the original grant date fair value no additional compensation expense was recorded in the consolidated statement of operations and comprehensive loss. The change in the fair value of the stock-based compensation liability of \$45,000 and (\$73,000) for the three months ended September 30, 2014 and for the nine months ended September 30, 2014, respectively, was recorded as an adjustment to Contributed Surplus.

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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.

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 May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers". This guidance is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those

goods or services. This guidance is effective for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. The Company will adopt this guidance on January 1, 2017. Companies may use either a full retrospective or a modified retrospective approach to adopt this guidance. The Company is evaluating which transition approach to use and its impact, if any, on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, "Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern." The guidance outlines management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and provides guidance on the related footnote disclosure. The amendments are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company is in the process of evaluating the impact of this guidance on its consolidated financial statement disclosures.

4. 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 shares 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.

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The following diluted securities have been excluded from the computation of diluted weighted-average shares outstanding as of September 30, 2014 and September 30, 2013 as the Company recorded a net loss in all periods and therefore they would be anti-dilutive (in thousands):

	September 30, 2014	September 30, 2013
Options to purchase common shares	1,380	290
Common share purchase warrants	1,001	919

5. Securities Available-for-Sale

Securities available-for-sale consisted of the following as of September 30, 2014 (in thousands):

	September 30, 2014			Estimated Fair Value
	Amortized Cost	Unrealized Gain	Unrealized Loss	
Commercial paper	\$6,798	\$ —	\$ —	\$ 6,798
U.S. government sponsored enterprise securities	3,302	1	—	3,303
Corporate debt securities	2,868	1	—	2,869
	\$12,968	\$ 2	\$ —	\$ 12,970

The amortized cost and estimated fair value of the Company securities available-for-sale by contractual maturity as of September 30, 2014 are shown below (in thousands):

	September 30, 2014			Estimated Fair Value
	Amortized Cost	Unrealized Gain	Unrealized Loss	
Within one year	\$12,968	\$ 2	\$ —	\$ 12,970
After one year	—	—	—	—
	\$12,968	\$ 2	\$ —	\$ 12,970

Securities available-for-sale consisted of the following as of December 31, 2013 (in thousands):

	December 31, 2013			
	Amortized	Unrealized		Estimated
	Cost	Gain	Loss	Fair
				Value
Commercial paper	\$9,798	\$ —	\$ —	\$ 9,798
U.S. government sponsored enterprise securities	17,007	2	(4)	17,005
Corporate debt securities	6,506	2	(1)	6,507
	\$33,311	\$ 4	\$ (5)	\$ 33,310

The amortized cost and estimated fair value of the Company securities available-for-sale by contractual maturity as of December 31, 2013 are shown below (in thousands):

	December 31, 2013			
	Amortized	Unrealized		Estimated
	Cost	Gain	Loss	Fair
				Value
Within one year	\$30,430	\$ 2	\$ (4)	\$ 30,428
After one year	2,881	2	(1)	2,882
	\$33,311	\$ 4	\$ (5)	\$ 33,310

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As of September 30, 2014, the Company has \$26.5 million of securities consisting of money market funds, commercial paper, U.S. government sponsored enterprise securities and corporate debt securities with maturities that range from one day to nine months with an overall average time to maturity of 2.7 months. The Company has the ability to liquidate these investments without restriction. The Company determines fair value for securities with Level 1 inputs through quoted market prices. The Company determines fair value for securities with Level 2 inputs through broker or dealer quotations or alternative pricing sources with reasonable levels of price transparency. The Company's Level 2 securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, typically utilizing third party pricing services or other observable market data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, and other industry and economic events. The Company's Level 3 inputs are unobservable inputs based on the Company's assessment that market participants would use in pricing the instruments.

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis for the periods presented (in thousands):

	September 30, 2014	Level 1	Level 2	Level 3
Assets:				
Money market funds	\$ 4,699	\$4,699	\$—	\$—
Commercial paper	15,597	—	15,597	—
U.S. government sponsored enterprise securities	3,303	—	3,303	—
Corporate debt securities	2,869	—	2,869	—
Total assets	\$ 26,468	\$4,699	\$21,769	\$—
Liabilities:				
Warrant liability	\$ —	\$—	\$—	\$—
Stock-based compensation liability	129	—	—	129
Total liabilities	\$ 129	\$—	\$—	\$ 129

	December 31, 2013	Level 1	Level 2	Level 3
Assets:				
Money market funds	\$ 55	\$ 55	\$—	\$—
Commercial paper	23,570	—	23,570	—
U.S. government sponsored enterprise securities	17,005	—	17,005	—
Corporate debt securities	6,507	—	6,507	—
Total assets	\$ 47,137	\$ 55	\$47,082	\$—

Liabilities:

Warrant liability	\$ 883	\$ —	\$—	\$883
Stock-based compensation liability	202	—	—	202
Total liabilities	\$ 1,085	\$ —	\$—	\$1,085

The Company calculates the fair value of the common share purchase warrants with exercise prices denominated in Canadian dollars (level 3) at each reporting period utilizing a Black-Scholes pricing model. The following inputs were utilized in the Black-Scholes pricing model:

	September 30, 2014		December 31, 2013	
Stock price at the end of each reporting period	\$ 2.93		\$ 3.70	
Weighted average exercise price	\$ 30.18		\$ 25.45	
Risk-free interest rate	0.13	%	0.62	%
Volatility	52.06	%	115.09	%
Dividend yield	0.00	%	0.00	%
Expected life in years	0.46		2.51	
Calculated fair value per common share purchase warrant	\$ —		\$ 0.96	

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The following table presents a reconciliation of the warrant liability measured at fair value using unobservable inputs (Level 3) (in thousands):

	Three Months Ended	Nine Months Ended
	September 30, 2014	September 30, 2014
Liabilities:		
Balance at beginning of period:	\$ —	\$ 883
Reclassification of fair value of warrant liability to equity as a result of the amendment to convert the exercise price of certain warrants from Canadian dollars to U.S dollars of the underlying common share purchase warrants	—	(834)
Change in fair value of warrant liability included in other income (expense), net	—	(49)
Balance at end of period:	\$ —	\$ —

The Company calculates the fair value of the stock-based compensation liability for those stock options with exercise prices denominated in Canadian Dollars (level 3) at each reporting period utilizing a Black-Scholes pricing model. The following inputs were utilized in the Black-Scholes pricing model:

	September 30, 2014	December 31, 2013	
Stock price at the end of each reporting period	\$ 2.93	\$ 3.70	
Weighted average exercise price	\$ 16.48	\$ 17.66	
Risk-free interest rate	0.93	%	1.00 %
Volatility	97.80	%	94.53 %
Dividend yield	0.00	%	0.00 %
Expected life in years	2.72	3.42	
Calculated fair value per stock option	\$ 0.73	\$ 1.17	

The following table presents a reconciliation of the stock-based compensation liability measured at fair value using unobservable inputs (Level 3) (in thousands):

Three Months Ended	Nine Months Ended
-----------------------------------	----------------------------------

	September 30, 2014	September 30, 2014
Liabilities:		
Balance at beginning of period:	\$ 84	\$ 202
Change in fair value of stock-based compensation liability recorded as an adjustment to contributed surplus	45	(73)
Balance at end of period:	\$ 129	\$ 129

There were no transfers of assets or liabilities between the fair value measurement classifications.

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Prepaid expenses as of September 30, 2014 and December 31, 2013 consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Prepaid insurance	\$ 385	\$ 292
Prepaid research and development expenses	2,689	3,218
Other prepaid expenses	27	88
	\$ 3,101	\$ 3,598

As of September 30, 2014 and December 31, 2013, prepaid research and development expenses includes \$2.6 million and \$2.7 million, respectively for upfront fees paid to our clinical research organizations assisting with our on-going Phase 3 clinical trial. The upfront fees will be relieved in future periods based upon work completed.

8. Accrued expenses

Accrued expenses as of September 30, 2014 and December 31, 2013 consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Accrued personnel related costs	\$ 841	\$ 1,063
Accrued interest	48	50
Accrued research and development expenses	1,738	713
Other accrued expenses	285	355
	\$ 2,912	\$ 2,181

9. Promissory notes

On June 30, 2014, we entered into a \$6.0 million Loan and Security Agreement with Oxford Finance LLC. The principal borrowed under the loan bears fixed interest of 9.504% per annum. The Company has the option to prepay the outstanding balance of the loan in full, subject to a prepayment fee of 1% to 3% depending upon when the

prepayment occurs. Upon the final repayment of the loan on the maturity date, by prepayment, or upon acceleration, the Company shall pay Oxford an additional fee of 5% of the principal amount of \$6.0 million. This additional fee is recorded as a debt discount and is being recognized as interest expense over the life of the loan utilizing the effective interest method. The repayment terms are monthly interest only payments through July 1, 2015 followed by 36 equal monthly payments of principal and interest.

In connection with the loan, the Company granted to Oxford a security interest in all of the Company's personal property now owned or hereafter acquired, excluding intellectual property and certain other assets.

As of September 30, 2014, the Company was in compliance with all covenants under the loan.

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As of September 30, 2014, the future contractual principal and final fee payments on our debt obligation are as follows (in thousands):

Year 1	\$290
Year 2	1,843
Year 3	2,026
Year 4	2,141
Total	\$6,300

The following table summarizes interest expense (in thousands) for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Simple interest	\$143	\$197	\$358	\$679
Amortization of debt discount	32	91	155	299
Amortization of promissory notes issuance costs	-	25	38	86
	\$175	\$313	\$551	\$1,064

10. Common stock purchase agreement with Aspire Capital

On May 16, 2014, the Company entered into a common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund LLC, or Aspire Capital. Under the Purchase Agreement, on any trading day on which the closing sale price of the Company's common shares exceeds \$2.00, the Company has the right, in its sole discretion, to present Aspire Capital with a purchase notice, directing Aspire Capital (as principal) to purchase up to 100,000 of the Company's common shares, per trading day, provided that the aggregate price of each such purchase shall not exceed \$1,000,000 per trading day. The Company can direct Aspire Capital to purchase an additional \$13 million of the Company's common shares over the remaining 26 months of the Purchase Agreement. Future purchases under the Purchase Agreement will be at a per share price equal to the lesser of:

- the lowest sale price of the Company's common shares on the purchase date; or
- the arithmetic average of the three lowest closing sale prices for the Company's common shares during the ten consecutive trading days ending on the trading day immediately preceding the purchase date.

Other than the initial purchase completed under the Purchase Agreement, there were no sales of common shares to Aspire Capital from May 16, 2014 through September 30, 2014.

11. Stock-based compensation plan

Equity awards

The Company's Amended and Restated 2011 Stock Option plan, or the Plan, provides for the granting of options for the purchase of common shares of the Company at the fair 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. Historically the Company granted options to residents of the United States with an exercise price denominated in Canadian dollars, the functional currency of Sophiris Bio Inc. Inc. prior to the Company's IPO. The Company grants options with an exercise price denominated in U.S. dollars

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	\$ 182	\$ 28	\$ 528	\$ 152
General and administrative	403	162	1,210	563
Total	\$ 585	\$ 190	\$ 1,738	\$ 715

As of September 30, 2014 there was \$1.0 million of total unrecognized compensation expense related to non-vested stock awards. As of September 30, 2014 the Company expects to recognize these costs over a weighted average period of approximately 1.1 years.

The fair values of options granted during the nine months ended September 30, 2014 and 2013 were estimated at the date of grant using the following weighted-average assumptions:

	Nine Months Ended September 30,	
	2014	2013
Expected life of the option term (years)	3.7	4.2
Risk-free interest rate	1.2 %	1.4 %
Dividend rate	0 %	0 %
Volatility	76.2 %	69.1 %
Forfeiture rate	5.3 %	8.8 %

The following table summarizes stock option activity, including options issued to employees, directors and non-employees (in thousands, except per share):

Options outstanding	Weighted average exercise price	Currency
--------------------------------	--	-----------------

Outstanding at January 1, 2014	1,362	\$ 7.10	US
Options granted	87	2.57	US
Options forfeited	(12) 29.89	CND
Options forfeited	(54) 4.41	US
Options expired	(3) 26.00	CND
Outstanding at September 30, 2014	1,380	\$ 6.69	US

The total amounts of options outstanding at September 30, 2014 include options with exercise prices denominated in Canadian dollars and U.S. dollars. The Canadian dollar amounts have been converted to U.S. dollars for purposes of the weighted average exercise price calculation using the grant date exchange rate for each Canadian dollar denominated option.

12. 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, or 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.

During the nine months ended September 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 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.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis in conjunction with our unaudited condensed consolidated financial statements and notes included below in this Quarterly Report on Form 10-Q (this Quarterly Report) and the audited consolidated financial statements and notes as of and for the year ended December 31, 2013 included with our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC. Operating results are not necessarily indicative of results that may occur in future periods.

This discussion and analysis contains forward-looking statements that involve a number of risks, uncertainties and assumptions. Actual events or results may differ materially from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, those set forth in "Item 1A. Risk Factors" in this Quarterly Report on Form 10-Q. All forward-looking statements included in this Quarterly Report on Form 10-Q are based on information available to us as of the time we file this Quarterly Report on Form 10-Q and, except as required by law, we undertake no obligation to update publicly or revise any forward-looking statements.

All dollar amounts are expressed in U.S. dollars unless otherwise noted. All amounts that are expressed on an as-converted from Canadian dollar to U.S. dollar basis are calculated using the conversion rate as of September 30, 2014 unless otherwise noted.

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 NASDAQ Global Market, or the NASDAQ. We are currently developing PRX302 as a treatment for the symptoms of benign prostatic hyperplasia, or BPH, commonly referred to as an enlarged prostate. 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.

In September 2014, we announced that we completed enrollment in a Phase 3 clinical trial of PRX302 (topsalysin) as a treatment for lower urinary tract symptoms of BPH. The randomized, double-blind and vehicle-controlled study will assess the safety and efficacy of a single intraprostatic injection of PRX302 (0.6 µg/g prostate) for the treatment of BPH. The primary endpoint is the International Prostate Symptom Score (IPSS) total score change from baseline over 52 weeks. Secondary endpoints include Qmax (maximum urine flow) change from baseline (maximum urine flow) over 52 weeks.

In May 2014, we announced that we intend to initiate a proof of concept study for PRX302 as a treatment for localized low to intermediate risk prostate cancer. We expect to initiate this study prior to the end of the first quarter of 2015.

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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 in 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 of Kissei or any future collaborator, result 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.

Essentially all of our research and development expenses related to PRX302 during the three and nine months ended September 30, 2014 and 2013. We recognized research and development expenses as follows (in thousands):

	Three Months Ended September 30, 2014		Nine Months Ended September 30, 2013	
Clinical research and development	\$6,074	\$1,230	\$17,165	\$4,225
Pre-clinical research and development	-	-	2	2
Manufacturing	454	859	2,934	1,764
Stock-based compensation expense	182	28	528	152
	\$6,710	\$2,117	\$20,629	\$6,143

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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 through our first Phase 3 clinical trial for the treatment of symptoms of BPH and we initiate a proof of concept study of PRX302 for localized low to intermediate risk prostate cancer. 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. 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 U.S. publicly traded company. These increases will likely include professional fees and directors' and officers' liability insurance premiums.

Interest Expense

Interest expense primarily represents interest payable to Oxford Finance, LLC, or Oxford, amortization of our debt discount and issuance costs associated with both our original loan and our new loan with Oxford.

Interest Income

We earn interest income from interest-bearing cash and investment accounts.

Gain on Revaluation of Warrant Liability

We changed our functional currency from the Canadian dollar to the U.S. dollar subsequent to the completion of our initial public offering on the NASDAQ effective August 16, 2013.

Subsequent to the change in functional currency, the Company calculates the fair value of its warrants with exercise prices in Canadian dollars utilizing the Black Scholes pricing model and classified this fair value as a long term liability in accordance with Accounting Standards Codification, or ASC, 815, “*Derivatives and Hedging*”. At each reporting period subsequent to the change in the Company’s functional currency, we 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 consolidated statement of operations and comprehensive loss.

Other Income (Expense), Net

Other income (expense), net consists primarily of foreign exchange gains and losses and on occasion income or expense of an unusual 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

The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and the revenues and expenses incurred during the reported periods. We believe that the estimates, assumptions and judgments involved in the accounting policies described in Management’s Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2013 have the greatest potential impact on our financial statements, so we consider them to be our critical accounting policies and estimates. There were no material changes to our critical accounting policies and estimates during the quarter ended September 30, 2014.

Table Of Contents**Results Of Operations***Comparison of the three months ended September 30, 2014 and 2013*

The following table summarizes the results of our operations for the three months ended September 30, 2014 and 2013, together with the changes in those items in dollars (in thousands):

	Three Months Ended September 30,		Change 2014 vs. 2013
	2014	2013	
Research and development expenses	6,710	2,117	4,593
General and administrative expenses	1,370	883	487
Interest expense	(175)	(313)	138
Interest income	10	—	10
Gain on revaluation of warrant liability	—	195	(195)
Other income (expense), net	21	166	(145)

Research and development expenses. Research and development expenses were \$6.7 million in the three months ended September 30, 2014 compared to \$2.1 million in the three months ended September 30, 2013. The increase in research and development costs is primarily due to a \$4.8 million increase in clinical costs associated with our Phase 3 clinical trial of PRX302, which began enrolling patients in October 2013 and an increase in stock-based compensation expense of \$0.2 million. This increase is offset by a decrease of \$0.4 million in the costs associated with manufacturing activities for PRX302.

General and administrative expenses. General and administrative expenses were \$1.4 million in the three months ended September 30, 2014 compared to \$0.9 million for the three months ended September 30, 2013. The increase from the three months ended September 30, 2013 to the three months ended September 30, 2014 is due to the increase in personnel related costs of \$0.1 million and an increase in stock-based compensation expense of \$0.2 million as a result of the inclusion of three months of expense associated with stock options granted to employees and directors in October 2013. The remaining \$0.2 million increase is associated with an increase in accounting and auditing fees and corporate insurance period over period.

Interest expense. Interest expense was \$0.2 million in the three months ended September 30, 2014 compared to \$0.3 million in the same period in 2013. The Company pays down the outstanding principal balance on its promissory notes by making fixed monthly principal and interest payments, as a result the decrease in interest expense period over period is directly associated with a decrease in the outstanding principal balance from 2013 to 2014.

Interest income. Interest income of \$10,000 was recorded for the three months ended September 30, 2014 as a result of interest earned on interest-bearing cash and investment accounts.

Gain on revaluation of warrant liability. Gain on revaluation of the warrant liability was \$0.2 million for the three months ended September 30, 2013. The non-cash gain is associated with the change in the fair value of our warrant liability. The fair value of the warrant liability was \$0 at September 30, 2014. The fair value is calculated utilizing the Black-Scholes pricing model.

Other income, net. Other income, net was \$21,000 for the three months ended September 30, 2014 compared to \$0.2 million other income, net for the three months ended September 30, 2013. This change was primarily due to a \$0.1 million decrease in foreign exchange losses associated with foreign currency transactions.

Table Of Contents*Comparison of the nine months ended September 30, 2014 and 2013*

The following table summarizes the results of our operations for the nine months ended September 30, 2014 and 2013, together with the changes in those items in dollars (in thousands):

	Nine Months Ended September 30,		Change 2014 vs. 2013
	2014	2013	
License revenue	\$—	\$5,000	\$(5,000)
Research and development expenses	20,629	6,143	14,486
General and administrative expenses	4,316	3,009	1,307
Interest expense	(551)	(1,064)	513
Interest income	40	—	40
Gain on revaluation of warrant liability	49	195	(146)
Other income (expense), net	(27)	(190)	163
Income tax expense	—	500	(500)

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

Research and development expenses. Research and development expenses were \$20.6 million in the nine months ended September 30, 2014 compared to \$6.1 million in the nine months ended September 30, 2013. The increase in research and development costs is primarily due to a \$13.7million increase in costs associated with our Phase 3 clinical trial of PRX302, which began enrolling patients in October 2013, and a \$1.3 million increase in the costs associated with manufacturing activities for PRX302. These increases are offset by a decrease of \$0.4 million for license fees paid in 2013 to UVIC and Johns Hopkins associated with our \$5.0 million non-refundable milestone payment from Kissei and a decrease of \$0.5 million associated with our completed Transrectal safety study. Research and development expenses included stock-based compensation expense of \$0.5 million for the nine months ended September 30, 2014 as compared to \$0.2 million for the nine months ended September 30, 2013.

General and administrative expenses. General and administrative expenses were \$4.3 million for the nine months ended September 30, 2014 compared to \$3.0 million for the nine months ended September 30, 2013. The increase

from the nine months ended September 30, 2013 to the nine months ended September 30, 2014 is due to an increase in personnel related expenses of \$0.3 million, an increase in directors and officers insurance of \$0.2 million as a result of our initial public offering on the NASDAQ in August 2013 and an increase in stock-based compensation expense of \$0.6 million as a result of the inclusion of nine months of expense associated with stock option grants to employees and directors in October 2013.

Interest expense. Interest expense was \$0.6 million in the nine months ended September 30, 2014 compared to \$1.1 million in the same period in 2013. The Company pays down the outstanding principal balance on its promissory notes by making fixed monthly principal and interest payments, as a result the decrease in interest expense from period to period is directly associated with a decrease in the outstanding principal balance from 2013 to 2014.

Interest income. Interest income of \$40,000 was recorded for the nine months ended September 30, 2014 as a result of interest earned on interest-bearing cash and investment accounts.

Gain on revaluation of warrant liability. Gain on revaluation of the warrant liability was \$49,000 for the nine months ended September 30, 2014 compared to \$0.2 million for the nine months ended September 30, 2013.

Other expense, net. Other expense, net was \$27,000 for the nine months ended September 30, 2014 compared to \$0.2 million for the nine months ended September 30, 2013. This change was primarily due to a \$0.2 million decrease in foreign exchange losses associated with foreign currency transactions.

Income tax expense. The \$5.0 million milestone payment that we recorded from Kissei during the nine months ended September 30, 2013 was subject to a 10% Japanese withholding tax. As a result, we recorded income tax expense of \$0.5 million for the nine months ended September 30, 2013.

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Liquidity and Capital Resources

Since our inception, our operations have been primarily financed through public and private equity sales, debt financing and payments from Kissei. Since inception, we have devoted our resources to funding and conducting research and development programs, including discovery research, preclinical studies and clinical trial activities.

At September 30, 2014, we had cash, cash equivalents and securities available-for-sale of \$29.1 million and net working capital of \$25.3 million. In May 2014 we entered into a common stock purchase agreement with Aspire Capital Fund, LLC, or Aspire Capital which provides that Aspire Capital is committed to purchase up to an aggregate of \$15.0 million of our common shares over the approximately 30 month term of the agreement. Upon the execution of the agreement, we sold to Aspire Capital 604,230 common shares which resulted in net proceeds of \$1.9 million. Over the remaining 26 months the Company has the right, subject to certain limitations including but not limited to the Company's closing stock price not falling below \$2.00 on the date of any directed purchase, to direct Aspire Capital to purchase up to an additional \$13 million of our common shares. There were no additional sales of common shares to Aspire Capital during the three months ended September 30, 2014.

On June 30, 2014, we entered into a new loan and security agreement with Oxford pursuant to which Oxford has loaned a principal amount of \$6.0 million to refinance our then existing term loan with Oxford and to provide additional working capital. The principal amount was used by us to settle approximately \$2.9 million of outstanding principal on our then existing term loan, to settle accrued interest on such term loan, to settle other fees and expenses, including approximately \$0.7 million in an accrued final payment due under the then existing term loan, and the remaining cash proceeds of approximately \$2.3 million will be used for general corporate purposes

The principal borrowed under the new loan bears a fixed interest of 9.504% per annum, which interest shall be payable monthly in arrears. Upon the earliest to occur of (i) the maturity date, (ii) the date we prepay all outstanding amounts under the new loan, or (iii) the date that all amounts under the new loan become due and payable, we shall pay Oxford an additional fee of 5% of the original principal amount. The repayment terms of the new loan are monthly interest only payments through July 1, 2015 followed by 36 months of equal principal and interest payments.

We expect that our current cash, cash equivalents and securities available-for-sale as of September 30, 2014 will be sufficient to fund our operations for at least the next 12 months, assuming that we do not initiate the second Phase 3 clinical trial. The following table shows a summary of our cash flows for the nine months ended September 30, 2014 and 2013 (in thousands):

**Nine Months
Ended September
30,
2014 2013**

Net cash provided by (used in):		
Operating activities	\$(19,794)	\$(8,822)
Investing activities	20,302	(3)
Financing activities	839	53,913
Effect of exchange rate changes on cash and cash equivalents	(12)	(70)
Net increase in cash and cash equivalents	\$1,335	\$45,018

Operating Activities

Net cash used in operating activities increased to \$19.8 million for the nine months ended September 30, 2014 compared to \$8.8 million for the nine months ended September 30, 2013. The increase in net cash used in operating activities of \$11.0 million was primarily due to the net cash outflow impact of the increase in our net loss from period to period. The increase in our net loss from the nine months ended September 30, 2013 to the nine months ended September 30, 2014 is primarily a result of the increase in our research and development expenses as a result of an increase in activities associated with our on-going Phase 3 clinical trial of PRX302.

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Investing Activities

Net cash provided by investing activities was \$20.3 million for the nine months ended September 30, 2014, compared to \$3,000 net cash used in investing activities for the nine months ended September 30, 2013. The increase in net cash provided by investing activities during the nine months ended September 30, 2014 represents the usage of the proceeds from the maturity of securities classified as available-for-sale to fund our operations and to a lesser extent to purchase securities with maturities less than 90 days which are classified as cash and cash equivalents.

Financing Activities

Net cash provided by financing activities was \$0.8 million for the nine months ended September 30, 2014 as compared to \$53.9 million net cash used in financing activities for the nine months ended September 30, 2013. The cash provided by financing activities for the nine months ended September 30, 2014 reflects the proceeds of \$1.9 million, net from the common share purchase by Aspire Capital. The cash provided by financing activities also includes cash received from Oxford of \$2.4 million from our new loan. These funds are offset by the settlement of our outstanding principal of \$3.4 million due under the original loan. The cash provided in financing activities during the nine months ended September 30, 2013 includes \$57.8 million, net from our U.S. public offering. These funds are offset by \$3.9 million of principal payments on our original loan with Oxford.

Future Operations

We have devoted substantial resources to developing PRX302, protecting and enhancing our intellectual property 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, debt financing and payments from Kissei.

We expect that we will require additional capital to complete development of PRX302, including conducting our second planned Phase 3 clinical trial and any other clinical trials of PRX302 for the treatment of localized low to intermediate risk prostate cancer other than our planned proof of concept study, to obtain regulatory approval of and to commercialize PRX302.

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, which may include the sale of shares to Aspire Capital under our common share purchase agreement, debt financings, by establishing additional strategic collaborations for PRX302 or from exercise of outstanding common share purchase warrants and stock options.

Table Of Contents**Contractual Obligations and Commitments**

The following is a summary of our contractual obligations as of September 30, 2014 (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⁾	\$315	\$118	\$197	\$—	\$ —
Principal and interest payable under promissory notes ⁽²⁾	7,695	860	4,613	2,222	—
Total	\$8,010	\$978	\$4,810	\$2,222	\$ —

We currently lease an office facility comprising our headquarters in San Diego, California under a non-cancelable (1) lease. The lease, as amended, expires in May 2017 and the minimum rent is \$8,729 per month, subject to annual cost of living increases, plus our pro rata share of certain operating costs and other expenses.

In June 2014, we entered into a new loan and security agreement with Oxford. The principal borrowed under the new loan bears a fixed interest of 9.504% per annum, which interest shall be payable monthly in arrears. Upon the (2) earliest to occur of (i) the maturity date, (ii) the date we prepay all outstanding amounts under the new loan, or (iii) the date that all amounts under the new loan become due and payable, we shall pay Oxford an additional fee of 5% of the original principal amount or \$0.3 million. The repayment terms of the new loan are monthly interest only payments through July 1, 2015 followed by 36 equal monthly payments of principal and interest.

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.

Recently adopted accounting pronouncements

On June 10, 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-10, “*Development Stage Entities (Topic 915) – Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation,*” which eliminates the concept of a development stage entity in its entirety from current accounting guidance and provides for certain amendments to the consolidation guidance in Topic 810 in the ASC. Prior to the issuance of this guidance we were considered a development stage entity and as a result we included certain inception-to-date disclosures in its financial statements. The guidance related to the elimination of the concept of a development stage entity is effective for public companies for annual reporting periods beginning after December 15, 2014, and interim periods therein. The amendment of the consolidation guidance in Topic 810 is effective for public companies for annual reporting periods beginning after December 15, 2015. Early adoption of the new standard was permitted. ASU No. 2014-10 was adopted by us during the quarter ended June 30, 2014. As such all inception-to-date disclosures have been removed from these condensed consolidated financial statements.

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Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board issued authoritative accounting guidance related to revenue from contracts with customers. This guidance is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. This guidance is effective for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. We will adopt this guidance on January 1, 2017. Companies may use either a full retrospective or a modified retrospective approach to adopt this guidance. We are evaluating which transition approach to use and its impact, if any, on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, "Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern." The guidance outlines management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and provides guidance on the related footnote disclosure. The amendments are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. We are in the process of evaluating the impact of this guidance on our consolidated financial statement disclosures.

Item 3. Qualitative and Quantitative Disclosures 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 accounts payable. Changes in foreign currency exchange rates can create foreign exchange gains or losses to us. 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 nine months ended September 30, 2014 and 2013, 18.1% and 33%, respectively, of our operating expenses were denominated in currencies other than the U.S. dollar. We have minimal direct exposure to interest rate risks as we do not have variable rate financial liabilities. In addition, our Oxford loan has a fixed interest rate of 9.504% therefore fluctuations in interest rates do not have an effect on the total outstanding principal due.

We invest our excess cash in investment-grade, interest-bearing securities. The primary objective of our investment activities is to preserve principal and liquidity. To achieve this objective, we invest in money market funds and high quality marketable debt instruments of corporations, financial institutions and government sponsored enterprises with contractual maturity dates of generally less than three years. We do not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt. If a 10% change in interest rates were to have occurred on September 30, 2014, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of September 30, 2014, we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2014.

Changes in Internal Control Over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our chief executive officer and our principal financial officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II.-OTHER INFORMATION

Item 1a. Risk Factors

You should consider carefully the following risk factors, together with all of the other information included or incorporated in this Quarterly Report, before making your decision whether to purchase or sell shares of our common stock. Each of these risk factors, either alone or taken together, could adversely affect our business, operating results, growth prospects and financial condition, as well as adversely affect the value of an investment in our common shares. If that were to happen, the trading price of our common stock could decline. There may be additional risks that we do not presently know of or that we currently believe are immaterial which could also impair our business and financial position. We have marked with an asterisk () those risk factors that reflect changes from the risk factors included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 14, 2014.*

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 and for the treatment of localized low to intermediate risk prostate cancer. We have not completed the development of any product candidates and, accordingly, have not begun to commercialize, or generate any product revenues from any product candidate. PRX302 requires significant additional clinical testing and investment prior to seeking marketing approval. A commitment of substantial resources by us and potential partners will be required to conduct time-consuming Phase 3 clinical trials for PRX302 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. 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.

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

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

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.

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

- warning letters;

- civil and criminal penalties;

- injunctions;

- withdrawal of approved products;

- product seizure or detention;

- product recalls;

- total or partial suspension of production; and

- refusal to approve pending BLAs or supplements to approved BLAs.

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

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

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

Based on the results from our Phase 2 clinical trials, we are currently conducting a Phase 3 clinical trial of PRX302 and expect to conduct one additional Phase 3 clinical trial for PRX302 to examine whether PRX302 will effectively relieve BPH symptoms as measured at three months and 12 months following treatment. The first of our two planned Phase 3 clinical trials, in which we completed enrollment in September 2014, will use the International Prostate Symptom Score, or IPSS, outcome measure evaluated at 12 months as the primary endpoint, which is consistent with clinical trials of another injectable currently under development by a third party for the treatment of the symptoms of BPH. We have not submitted a special protocol assessment, or SPA, which drug development companies sometimes use to obtain an agreement with the FDA concerning the design and size of a clinical trial intended to form the primary basis of an effectiveness claim. Without the concurrence of the FDA on an SPA or otherwise, we cannot be certain that the design, conduct and data analysis approach for our ongoing and planned Phase 3 clinical trials will generate data sufficient to establish the effectiveness of PRX302 for treatment of BPH symptoms to the FDA's satisfaction, and therefore allow us to submit or receive approval of a BLA for PRX302. If the FDA requires us, or we otherwise determine, to amend our protocols, change our clinical trial designs, increase enrollment targets or conduct additional clinical trials, our ability to obtain regulatory approval on the timeline we have projected would be jeopardized and we could be required to make significant additional expenditures related to clinical development.

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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 our ongoing and planned Phase 3 clinical trials that delay enrollment or completion of such clinical trials and could delay regulatory approval of PRX302. Any failure to obtain approval for PRX302 on the timeline that we currently anticipate, or at all, would have a material and adverse impact on our business, prospects, financial condition and results of operations.

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

****We expect to receive an interim analysis of the results of our first Phase 3 clinical trial of PRX 302 in late 2014 after all of the enrolled patients complete three months in the trial. Because the results of early clinical trials are not necessarily predictive of future results, PRX302 may not have favorable results in the interim analysis or at completion of the ongoing Phase 3 clinical trial or in later clinical trials or receive regulatory approval.***

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

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

Further, the data collected from clinical trials with large patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of PRX302. Our one ongoing and additional planned Phase 3 clinical trials of PRX302 will enroll significantly more patients than we have enrolled in clinical trials of PRX302 to date. If PRX302

fails to demonstrate sufficient safety or efficacy, we would experience potentially significant delays in, or be required to abandon our development of, PRX302, which would have a material and adverse impact on our business, prospects, financial condition and results of operations.

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

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

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

- regulatory authorities may withdraw their approval of PRX302;

- regulatory authorities may require that we demonstrate a larger clinical benefit by conducting additional clinical trials for approval to offset the risk;

- regulatory authorities may require the addition of labeling statements or warnings that could diminish the usage of the product or otherwise limit the commercial success of PRX302;

- we may be required to change the way PRX302 is administered;

- we may choose to recall, withdraw or discontinue sale of PRX302;

- we could be sued and held liable for harm caused to patients;

- we may not be able to enter into collaboration agreements on acceptable terms and execute on our business model;
and

- our reputation may suffer.

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

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

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

- raising sufficient capital to fund our second planned Phase 3 clinical trial;
- obtaining regulatory approval, or feedback on trial design necessary, to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- identifying, recruiting and enrolling suitable patients to participate in a clinical trial;
- catastrophic loss of drug product due to shipping delays or delays in customs in connection with delivery of drug product to foreign countries for use in clinical trials;

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- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining sufficient quantities of PRX302 and the diluent used with PRX302 for use in clinical trials;
- having patients complete a trial or return for post-treatment follow-up;
- adding new clinical trial sites;
- political unrest in countries where our clinical sites may be located, including in Russia and the Ukraine where we have current sites;
- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions;
- unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;
- obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site; and
- retaining patients who have initiated a clinical trial but may withdraw due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues.

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

We may face competition to enroll BPH patients in our second 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.

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

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

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

We have a CRO in Russia and have clinical sites for our ongoing Phase 3 clinical trial in Russia and the Ukraine. None of these sites are in the formerly active war zone of Eastern Ukraine and to date, none of these sites have been impacted by the hostilities in Ukraine or by the existing and announced United States, European or other sanctions against Russia. However, we cannot assure you that this will not change, and we continue to monitor the situation. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trial unless we are able to transfer the care of those patients to another

qualified clinical trial site. Further, if our relationship with any of our CROs is terminated, we may be unable to enter into arrangements with alternative CROs on commercially reasonable terms, or at all.

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

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

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

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

Our predecessor, Protox Pharmaceuticals Inc., was incorporated in January 2002. We were formed in May 2003 under the predecessor to the British Columbia Business Corporations Act, or the BCBCA, by the amalgamation of Stratos Biotechnologies Inc., Nucleus BioScience Inc. and Brightwave Ventures Inc. under the name SNB Capital Corp. In July 2004, we acquired all the shares of Protox Pharmaceuticals Inc. in a plan of arrangement under the BCBCA and changed its name to Protox Therapeutics Inc. In 2011, we formed a wholly-owned U.S. subsidiary incorporated in Delaware, Protox Therapeutics Corp. In 2012, we changed our name to Sophiris Bio Inc. and changed the name of our subsidiary to Sophiris Bio Corp. In 2012, Sophiris Bio Corp. formed a wholly-owned subsidiary incorporated in Delaware, Sophiris Bio Holding Corp. We face considerable risks and difficulties as a company with limited operating history, particularly as a consolidated entity with an operating subsidiary that also has a limited operating history. If we do not successfully address these risks, our business, prospects, operating results and financial condition will be materially and adversely harmed. Our limited operating history makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected. We have limited experience as a consolidated operating entity, and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical or biotechnology areas.

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

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

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

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

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

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

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

Sales of PRX302 outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries must also approve the manufacturing and marketing of the product candidates in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to approval. We may decide to submit an MAA to the EMA for approval in the EEA. As with the FDA, obtaining approval of an MAA from the EMA is a similarly lengthy and expensive process and the EMA has its own procedures for approval of product candidates. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the EEA also have requirements for approval of

drug candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of PRX302 will be harmed and our business will be adversely affected.

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

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

- fines, warning letters or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;

- product seizure or detention, or refusal to permit the import or export of products;
 - and

- injunctions, the imposition of civil or criminal penalties, or exclusions.

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

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

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**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 September 30, 2014 we had ten full-time employees. In addition, we have engaged part-time individual consultants to assist us with establishing accounting systems, managing vendors and CROs, project management, regulatory compliance and business development. We will need to expand our managerial, operational, financial and other resources in order to manage our operations and clinical trials, continue our research and development activities, and commercialize our product candidate. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- manage our clinical trials effectively, including our two planned Phase 3 clinical trials of PRX302;

- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors and other third parties;
 - continue to improve our operational, financial and management controls and reporting systems and procedures;

- attract and retain sufficient numbers of talented employees; and

- manage our regulatory compliance oversight and infrastructure.

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

**The terms of our senior debt facility require us to meet certain operating 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 June 2014, we entered into a \$6 million senior secured loan with Oxford Finance LLC, or Oxford, which we refer to as the New Loan. The New 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 July 1, 2018, assuming there is no default that results in acceleration of the debt. In connection with the original loan dated July 2011, 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 New 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 New 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 New 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.

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

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

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

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.

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

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

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

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

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

depend on a number of factors, including:

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

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

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

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

Government health administration authorities, private health insurers and other organizations establish coverage and reimbursement policies for new products, including product candidates like PRX302. In particular, in the United States, private health insurers and other third-party payers often provide reimbursement for treatments based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the United States, the EEA and other significant or potentially significant markets for our product candidate, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in Canada and the EEA will put additional pressure on product pricing, coverage, reimbursement and utilization, which may adversely affect our product sales and results of operations. These pressures can arise from policies and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, coverage and reimbursement policies and

pricing in general. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers.

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

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

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

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

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

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

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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.

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

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

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

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

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

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

- decreased demand for our product or product candidates that we may develop;
- injury to our reputation;

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- 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;
- 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 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.

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

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

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

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

time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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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 \$113 million from the sale of equity securities in private placements and public offerings, \$21 million from the issuance of debt securities, and \$9 million from the exercise of common share purchase warrants. We expect to continue to spend substantial amounts to continue clinical development of PRX302, including the completion of our ongoing Phase 3 clinical trial for the treatment of the symptoms of BPH, the conduct of our planned Phase 3 clinical trials for the treatment of the symptoms of BPH, our planned proof of concept study of PRX302 for the treatment of localized low to intermediate risk prostate cancer and to pay for future required clinical development, and seek regulatory approval for PRX302, to repay our Oxford loan and to launch and commercialize PRX302, if approved.

We expect that our existing cash, together with interest thereon, will be sufficient to fund our operations for at least the next 12 months, assuming that we do not initiate the second 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 ongoing Phase 3 clinical trial for the treatment of the symptoms of BPH or our planned Phase 2 clinical trial for the treatment of localized low to intermediate risk prostate cancer may encounter technical, enrollment or other issues that could delay the trial or cause our development costs to increase more than we expected, depleting our cash earlier than expected and jeopardizing our ability to obtain or to use the trials' results in the absence of additional funding. Any clinical development efforts beyond our ongoing Phase 3 clinical trial in BPH and our planned Phase 2 clinical trial in localized low to intermediate risk prostate cancer will require new funding.

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

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

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

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

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

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

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

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

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

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

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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 financings may be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing shareholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

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

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

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

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

At September 30, 2014, we had \$16.2 million of cash and cash equivalents and \$13.0 million in securities available-for-sale. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents since September 30, 2014, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of cash equivalents owned by us.

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

We currently incur expenses denominated in foreign currencies, specifically in connection with our manufacturing and supply agreement with Boehringer Ingelheim RCV GmbH & Co KG for the manufacture of PRX302, for which payments are denominated in euro. In addition, we expect that we will utilize numerous clinical trial sites as part of our first Phase 3 clinical trial for PRX302 which will be located in various countries outside of the United States. These clinical trial sites may 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 nine months ended September 30, 2014 and 2013, 18.1% and 33%, respectively, of our operating expenses were denominated in currencies other than the U.S. dollar. Going forward we anticipate that our sales and expenses, if any, will be denominated in the local currency of the country in which they occur. We may decide to manage this risk by hedging our foreign currency exposure, principally through derivative contracts. Even if we decide to enter into such hedging transactions, we cannot be sure that such hedges will be effective or that the costs of such hedges will not exceed their benefits. Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies, primarily the euro, could result in material amounts of cash being required to settle the hedge transactions or could adversely affect our financial results.

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.

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

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

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

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

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

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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.

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

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

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

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

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

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

own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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Risks Related to Ownership of Our Common Shares

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

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

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

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

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

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

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

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

- the commencement, enrollment or results of our ongoing and planned Phase 3 clinical trials of PRX302 or any future clinical trials we may conduct, or changes in the development status of PRX302;
- any adverse development or perceived adverse development with respect to the FDA's review of our plan for our two Phase 3 clinical trials, or delay in our submission of a BLA to the FDA for PRX302;
- unanticipated serious safety concerns related to the use of PRX302;
- adverse regulatory decisions, including failure to receive regulatory approval for PRX302;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- our ability to obtain resources for us and our clinical trial programs on our desired schedule;
- inability to obtain adequate commercial supply for any approved product or inability to do so at acceptable prices;
- developments concerning our commercial partners, including but not limited to, those with manufacturers;
- competition from existing technologies and products or new technologies and products that may emerge;
- announcements of significant acquisitions, strategic partnerships, joint ventures, new products, capital commitments or other events by us or our competitors;
- the inability to establish collaborations or termination of a collaboration;

- actual or anticipated variations in our quarterly operating results;

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

- our cash position;

- announcement or expectation of additional financing efforts;

- issuances of debt or equity securities;

- our inability to successfully enter new markets or develop additional product candidates;
 - actual or anticipated fluctuations in our competitors' operating results or changes in their growth rate;

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

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- trading volume of our common shares on the NASDAQ and price;
- market conditions in our industry;
- overall performance of the equity markets and general political and economic conditions;
- introduction of new products or services by us or our competitors;
- additions or departures of key management, scientific or other personnel;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities or industry analysts;
- changes in the market valuation of similar companies;
- disputes or other developments related to intellectual property and other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies and product candidates;
- changes in laws or regulations and policies applicable to product candidates, including but not limited to clinical trial requirements for approvals;
- changes in accounting practices;
- significant lawsuits, including patent or shareholder litigation; and
- other events or factors, many of which are beyond our control.

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

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

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

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

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

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

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

We are at risk of securities class action litigation.

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

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

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

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

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common shares held by

non-affiliates exceeds \$700 million as of any June 30 before that time or if we have total annual gross revenue of \$1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than \$1.0 billion in non-convertible debt during any three year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

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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.

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

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

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

Risks Related To Being A Canadian Entity

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

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

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Item 2. Use of Proceeds

Use of Proceeds

As of September 30, 2014, we have utilized \$19.9 million of the net proceeds from our initial public offering on the NASDAQ to fund activities associated with our first Phase 3 clinical trial for PRX302, \$6.3 million for general corporate purposes and \$9.2 million for principal and interest payments on our term loan with Oxford Finance LLC.

We intend to use the remainder of the net proceeds to complete the first Phase 3 clinical trial of PRX302 and to fund other ongoing clinical development of PRX302, in addition to making monthly principal and interest payments on our term loan with Oxford Finance LLC. We will use any remaining proceeds from the offering for general corporate purposes. The amounts and timing of actual expenditures depend on numerous factors, including the ongoing status of and results from clinical trials as well as any unforeseen cash needs.

Repurchases of Equity Securities

There were no repurchases of equity securities during the third quarter of 2014.

Item 6. Exhibits

Exhibit number	Description of Exhibit	Incorporated by Reference or Attached Hereto
3.1	Certificate of Amalgamation of the Company, dated January 1, 2005	Incorporated by reference to the Registrant's Form S-1 (SEC File No. 333-186724) filed on February 15, 2013.
3.2		

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|-----|--|---|
| | Notice of Articles of the Company | Incorporated by reference to the Registrant's Form S-1 (SEC File No. 333-186724) filed on February 15, 2013. |
| 3.3 | Articles of the Company | Incorporated by reference to the Registrant's Form S-1 (SEC File No. 333-186724) filed on February 15, 2013. |
| 4.1 | Form of Common Share Certificate | Incorporated by reference to the Amendment No. 4 to the Registrant's Form S-1/A (SEC File No. 333-186724) filed on July 15, 2013. |
| 4.2 | Form of Common Share Purchase Warrant issued in connection with the Company's March 2010 Private Placement | Incorporated by reference to the Registrant's Form S-1 (SEC File No. 333-186724) filed on February 15, 2013. |
| 4.3 | Form of Common Share Purchase Warrant Issued in connection with the initial closing pursuant to our Investment Agreement by and between the Company, Warburg Pincus Private Equity X, L.P. and | Incorporated by reference to the Registrant's Form S-1 (SEC File No. 333-186724) filed on February 15, 2013. |

Warburg
Pincus X
Partners,
L.P.,
dated
September
28, 2010.

Form of
Common
Share
Purchase
Warrant
Issued in
connection
with the
subsequent
closings
pursuant
to our
Investment
Agreement

4.4

by and
between
the
Company,
Warburg
Pincus
Private
Equity X,
L.P. and
Warburg
Pincus X
Partners,
L.P.,
dated
September
28, 2010.

Incorporated by reference to the Registrant's Form S-1 (SEC File No. 333-186724)
filed on February 15, 2013.

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4.5	Common Share Purchase Warrant Issued to Oxford Finance LLC	Incorporated by reference to the Registrant's Form S-1 (SEC File No. 333-186724) filed on February 15, 2013.
4.6	Common Share Purchase Warrant Issued to Oxford Finance LLC	Incorporated by reference to the Registrant's Form S-1 (SEC File No. 333-186724) filed on February 15, 2013.
4.7	Registration Rights Agreement by and between the Company, Warburg Pincus Private Equity X, L.P. and Warburg Pincus X Partners, L.P., dated November 19, 2010	Incorporated by reference to the Amendment No. 5 to the Registrant's Form S-1/A (SEC File No. 333-186724) filed on August 2, 2013.
4.8	Omnibus Amendment to	Incorporated by reference to the Current Report on Form 8-K filed on February 6, 2014.

Warrants
to
Purchase
Common
Shares
dated
January
31,
2014,
2014
by
and
between
the
Company
and
Warburg
Pincus
Private
Equity
X,
L.P.
and
Warburg
Pincus
X
Partners,
L.P.

Omnibus
Amendment
to
Warrants
to
Purchase
Common
Shares
dated
February
14,
2014
by
and
between
the
Company
and
Oxford
Finance
LLC

4.9

Incorporated by reference to the Current Report on
Form 8-K filed on February 18, 2014

4.10	Common Share Purchase Warrant Issued to Oxford Finance LLC dated June 30, 2014	Incorporated by reference to the Quarterly Report on Form 10-Q filed on August 7, 2014.
4.11	Common Share Purchase Warrant Issued to Oxford Finance LLC dated June 30, 2014	Incorporated by reference to the Quarterly Report on Form 10-Q filed on August 7, 2014.
10.1+	Officer Change in Control Severance Benefit Agreement by and between Randall E. Woods and the Company	Attached hereto.
10.2+	Officer Change in Control Severance Benefit	Attached hereto.

Agreement
by
and
between
Allison
Hulme
and
the
Company

Officer
Change
in
Control
Severance
Benefit
Agreement
by
and
between
Peter
T.
Slover
and
the
Company

10.3+

Attached hereto.

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Exhibit number	Description of Exhibit	Incorporated by Reference or Attached Hereto
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended	Attached hereto.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended	Attached hereto.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Attached hereto.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Attached hereto.
101.INS	** XBRL Instance Document	Attached hereto.
101.SCH	** XBRL Taxonomy Extension Schema Document	Attached hereto.
101.CAL	** XBRL Taxonomy Extension Calculation Linkbase Document	Attached hereto.
101.DEF	** XBRL Taxonomy Extension Definition Linkbase Document	Attached hereto.
101.LAB	** XBRL Taxonomy Extension Label Linkbase Document	Attached hereto.
101.PRE	** XBRL Taxonomy Extension Presentation Linkbase Document	Attached hereto.

+Indicates management contract or compensatory plan.

* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Quarterly Report on Form 10-Q is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act, is deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

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SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California, on the 12th day of November 2014.

SOPHIRIS BIO INC.

By: /s/ Randall E. Woods

Randall E. Woods

Chief Executive Officer and President

By: /s/ Peter T. Slover

Peter T. Slover

Chief Financial Officer

61.

Exhibit 10.1

OFFICER CHANGE IN CONTROL SEVERANCE BENEFIT AGREEMENT

This **OFFICER CHANGE IN CONTROL SEVERANCE BENEFIT AGREEMENT** (the “*Agreement*”) is made and entered into effective as of September 9, 2014, (the “*Effective Date*”), by and between Sophiris Bio Inc., a British Columbia, Canada corporation (the “*Company*”), and Randall E. Woods (the “*Officer*”). The Company and the Officer are hereinafter collectively referred to as the “Parties”, and individually referred to as a “Party”.

RECITALS

WHEREAS, the Company desires to continue to employ Officer to provide personal services to the Company in that capacity, and wishes to provide Officer with certain severance benefits in return for Officer’s services, and Officer wishes to be so employed and to receive such benefits; and

WHEREAS, the Company and Officer wish to enter into this Agreement to define their mutual rights and duties with respect to Officer’s severance benefits;

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, and for other good and valuable consideration, the Parties, intending to be legally bound, agree as follows:

AGREEMENT

1. EMPLOYMENT.

1.1 Loyalty; At Will Employment. During the Officer’s employment by the Company, the Officer shall devote Officer’s full business energies, interest, abilities and productive time to the proper and efficient performance of Officer’s duties as an employee of the Company unless otherwise approved in writing by the Company’s Board of

Directors (the “**Board**”). Officer’s employment with the Company is at will and not for any specified period and may be terminated at any time, with or without Cause, by either Officer or Company, subject to the provisions of Sections 3 and 4 below. This Agreement is additional to and does not supersede the terms of the Employment Agreement between the Officer and the Company originally entered into on August 16, 2012, as it may be subsequently amended from time to time (the “**Employment Agreement**”).

1.2 Termination of Obligations. In the event of the termination of the Officer’s employment with the Company, the Company shall have no obligation to pay Officer any base salary, bonus or other compensation or benefits, except: (i) as earned prior to the date of termination, (ii) as provided in Section 3, (iii) for benefits due to the Officer (and/or the Officer’s dependents) under the terms of the Company’s benefit plans, or (iv) as may otherwise be provided by the Officer’s Employment Agreement. To the extent permitted by applicable laws, the Company may offset any amounts Officer owes it or its subsidiaries against any amount it owes Officer pursuant to Section 3 of this Agreement.

1.3 Term. The term of this Agreement shall begin on the Effective Date and shall continue until Officer’s employment with the Company is terminated for any reason.

1.

2. DEFINITIONS.

For purposes of this Agreement, the following terms shall have the following meanings:

2.1 Cause. “Cause” for the Company to terminate Officer’s employment shall mean::

- (i) Officer’s repeated failure to satisfactorily perform his or her job duties, including but not limited to Officer’s refusal or failure to follow lawful and reasonable directions of the Board;
- (ii) Officer’s commission of an act that materially injures the business of the Company;
- (iii) Officer’s commission of an act constituting dishonesty, fraud, or immoral or disreputable conduct;
- (iv) Officer’s conviction of a felony, or conviction of any crime involving moral turpitude;
- (v) Officer’s engaging or in any manner participating in any activity which is directly competitive with or injurious to the Company, or which violates any material provisions of the Employment Agreement, this Agreement or any written agreement with the Company; or
- (vi) Officer’s use or intentional appropriation for Officer’s personal use or benefit of any funds, information or properties of the Company not authorized by the Company to be so used or appropriated.

The determination that the termination is for Cause shall be made by the Board in its sole discretion.

2.2 Change in Control. For purposes of this Agreement, “Change in Control” means:

(i) an acquisition by any person, entity or group within the meaning of Section 13(d) or 14(d) of the Exchange Act, or any comparable successor provisions (excluding any employee benefit plan, or related trust, sponsored or maintained by the Company or subsidiary of the Company or other entity controlled by the Company) of the beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act, or comparable successor rule) of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur solely because the level of ownership held by a person, entity or group exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, a person, entity or group becomes the owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities owned by such person, entity or group over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(ii) there is consummated a merger, consolidation, plan of arrangement or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation, plan of arrangement or similar transaction, the stockholders of the Company immediately prior thereto do not own, directly or indirectly, outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving entity in such merger, consolidation, plan of arrangement or similar transaction or more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation, plan of arrangement or similar transaction; or

(iii) there is consummated a sale or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportions as their ownership of the Company immediately prior to such sale, lease, license or other disposition.

2.

2.3 Covered Period. “*Covered Period*” means the period commencing one (1) month immediately prior to a Change in Control of the Company and ending eighteen (18) months immediately following a Change in Control of the Company.

2.4 Covered Termination. “*Covered Termination*” means a termination without Cause or resignation for Good Reason that occurs within the Covered Period. For such purposes, if the events giving rise to the Officer’s right to resign for Good Reason arise within the Covered Period, and the Officer’s resignation occurs not later than thirty (30) days after the expiration of the Cure Period (as defined below), such termination shall be a Covered Termination.

2.5 Good Reason. “*Good Reason*” for Officer to resign employment shall mean the occurrence of any of the following events without Officer’s written consent:

(i) a material reduction in Officer’s duties, authority, or responsibilities relative to the duties, authority, or responsibilities in effect immediately prior to such reduction;

(ii) the relocation of Officer’s principle place of employment resulting in an increase in Officer’s one-way commuting distance from his residence by at least forty (40) miles; and

(iii) a material reduction by the Company of Officer’s base salary, by more than ten percent (10%) (unless such reduction is made pursuant to an across the board reduction generally applicable to senior executives of the Company);

provided, however, that such termination by Officer shall only be deemed for Good Reason pursuant to the foregoing definition if (i) the Company is given written notice from Officer within thirty (30) days following the first occurrence of the condition that he considers to constitute Good Reason, describing the condition, and the Company fails to satisfactorily remedy such condition within thirty (30) days following such written notice (the “*Cure Period*”), and (ii) Officer resigns employment and service from all positions Officer holds with the Company effective no later than thirty (30) days following the end of the Cure Period.

2.6 Integration. The parties acknowledge that the definition of “for Cause” contained within this Agreement may differ from the definitions of “for Cause” contained within Officer’s stock option agreement or other equity award agreements. The Parties agree that unless it is determined that Officer shall be terminated for “Cause” as defined in this Agreement, there shall be no termination for “Cause” under any of Officer’s stock option agreements or other equity award agreements. Therefore, unless otherwise expressly provided in such equity award agreement, the definition of

“Cause” in this Agreement shall supersede and replace in its entirety any definition of “Cause” that may be included in Officer’s equity award agreements.

3. COMPENSATION UPON TERMINATION.

3.1 Death or Disability. If the Officer’s employment with the Company is terminated as a result of death or disability, the Company shall pay to Officer, and/or Officer’s heirs, the Officer’s base salary and accrued and unused vacation benefits earned through the date of termination at the rate in effect at the time of termination, less standard deductions and withholdings, and the Company shall thereafter have no further obligations to the Officer and/or Officer’s heirs under this Agreement.

3.2 With Cause or Without Good Reason. If the Officer’s employment with the Company is terminated by the Company for Cause or if the Officer terminates employment with the Company without Good Reason, the Company shall pay the Officer’s base salary and accrued and unused vacation benefits earned through the date of termination at the rate in effect at the time of termination, less standard deductions and withholdings, and the Company shall thereafter have no further obligations to the Officer under this Agreement.

3.3 Without Cause or for Good Reason Termination Outside of Covered Period. In the event Officer’s employment with the Company is terminated by the Company without Cause or Officer resigns for Good Reason in each case at any time other than during the Covered Period, the Company shall pay the Officer’s base salary and accrued and unused vacation benefits earned through the date of termination at the rate in effect at the time of termination, less standard deductions and withholdings, and the Company shall thereafter have no further obligations to the Officer under this Agreement.

3.

3.4 Change in Control Related Severance Benefits. In the event that Officer's employment with the Company is terminated in a Covered Termination, and Officer signs the Release and Waiver of Claims as set forth as Exhibit A or such other form of release as the Company may require in order to comply with applicable laws (the "**Release**") on or within the time period set forth therein, but in no event later than forty-five (45) days after Officer's termination date, and allows such Release to become effective in accordance with its terms, then Officer will receive the following benefits:

(i) the equivalent of eighteen (18) months of the Officer's Base Salary (as defined below), less standard deductions and withholdings, which shall be paid in a single lump sum within five (5) days after the effective date of the Release or if later, the effective date of the Change in Control (if Officer's termination occurs prior to the Change in Control). "**Base Salary**" shall mean Officer's base pay (excluding incentive pay, premium pay, commissions, overtime, bonuses and other forms of variable compensation), at the rate in effect during the last regularly scheduled payroll period immediately preceding the date of the termination, but prior to any reduction that would give rise to the Officer's right to resign for Good Reason.

(ii) If Officer is eligible for and timely elects continued group health plan coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("**COBRA**") following Officer's termination, the Company will pay the Officer's COBRA group health insurance premiums for the Officer and his eligible dependents for a period of eighteen (18) months following the effective date of the Release or if later, the effective date of the Change in Control (if Officer's termination occurs prior to the Change in Control). (the "**COBRA Payment Period**"); provided, however, that any such payments will cease (or will not commence) if Officer voluntarily enrolls in a health insurance plan offered by another employer or entity during the period in which the Company is paying such premiums or if Officer becomes ineligible for COBRA coverage prior to or during such period. Officer is required to immediately notify the Company in writing of any such enrollment in a plan offered by another employer. For purposes of this Section 3.4(ii), references to COBRA premiums shall not include any amounts payable by Officer under an Internal Revenue Code Section 125 health care reimbursement plan.

Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Officer a taxable cash amount, which payment shall be made regardless of whether Officer or Officer's eligible family members elect health care continuation coverage (the "**Health Care Benefit Payment**"). The Health Care Benefit Payment shall be paid in monthly installments on the same schedule that the COBRA Premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company would have otherwise paid for COBRA insurance premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the earlier of (i) expiration of the COBRA Payment Period, or (ii) the date Officer voluntarily enrolls in a health insurance plan offered by another employer or entity.

(iii) The greater of 150% of: (A) Officer's last annual bonus amount that had been paid under the Company's current bonus plan or any successor bonus plan (the "**Bonus Plan**"), or (B) the last annual target bonus amount that was in

effect under the provisions of the Bonus Plan preceding Officer's termination date, (such greater amount is the "**Bonus Payment**"). The Bonus Payment shall be subject to all standard deductions and withholdings and shall be paid in a single lump sum within five (5) days after the later of (A) the effective date of the Release, or (B) the effective date of the Change in Control (if Officer's termination occurs prior to the Change in Control); and

(iv) Full accelerated vesting of all unvested shares subject to any outstanding stock options, restricted stock or other equity awards then held by Officer that are subject to vesting solely upon the passage of time and the Officer's continued services, such that all shares shall be vested and fully exercisable as of the effective date of the Release, or if later, the effective date of the Change in Control (if Officer's termination occurs prior to the Change in Control). In order to give effect to the foregoing provision, notwithstanding anything to the contrary set forth in Officer's equity award agreements that may provide for immediate forfeiture of unvested equity awards in connection with a termination of employment or a limited post-termination exercise period for vested options, following any termination of Officer's employment that is without Cause or for Good Reason and thus may potentially qualify as a Covered Termination if a Change in Control occurs within the one (1) month period thereafter, none of Officer's equity awards shall terminate with respect to any vested or unvested portion subject to such award before the later of (A) one (1) month following such termination, or (B) the effective date of the Release; provided, however, that such awards may still earlier terminate upon a Change in Control to the extent the awards will not be assumed, continued or substituted by the acquiring or continuing entity.

4.

3.5 No Duplicative Benefits Provided Under Agreement. Unless otherwise determined by the Company in its discretion, if the Officer is otherwise eligible to receive severance benefits under this Agreement that are of the same category and would otherwise duplicate the severance benefits available under the terms of the Employment Agreement (“*Duplicative Benefits*”) the Officer will receive severance benefits under the Employment Agreement in lieu of any benefits under this Agreement to the extent such benefits are Duplicative Benefits, and severance benefits will be provided under this Agreement only to the extent, if any, that the benefits provided under this Agreement are not Duplicative Benefits.

4. TAX COMPLIANCE.

4.1 Application of Internal Revenue Code Section 409A. Notwithstanding anything to the contrary herein, the following provisions apply to the extent severance benefits provided herein are subject to Section 409A of the Internal Revenue Code of 1986, as amended (the “*Code*”) and the regulations and other guidance thereunder and any state law of similar effect (collectively “*Section 409A*”). Severance benefits shall not commence until Officer has a “separation from service” for purposes of Section 409A. Each installment of severance benefits is a separate “payment” for purposes of Treas. Reg. Section 1.409A-2(b)(2)(i), and to the maximum extent such exemptions are available, the severance benefits are intended to satisfy the exemptions from application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, to the extent such exemptions are not available and Officer is, upon separation from service, a “specified employee” for purposes of Section 409A, then, solely to the extent necessary to avoid adverse personal tax consequences under Section 409A, the timing of the severance benefits payments shall be delayed until the earlier of (i) six (6) months and one day after Officer’s separation from service, or (ii) Officer’s death. The severance benefits are intended to qualify for an exemption from application of Section 409A or comply with its requirements to the extent necessary to avoid adverse personal tax consequences under Section 409A, and any ambiguities herein shall be interpreted accordingly.

4.2 Parachute Payment. If any payment or benefit Officer would receive pursuant to a Change in Control or otherwise (“*Payment*”) would (i) constitute a “parachute payment” within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “*Excise Tax*”), then such Payment shall be reduced to the Reduced Amount. The “*Reduced Amount*” shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Officer’s receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting “parachute payments” is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for Officer. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, Officer agrees to

promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, Officer will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

5.

The Company shall engage a nationally recognized accounting or consulting firm to perform the foregoing calculations. If the firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, then the Company shall appoint another nationally recognized accounting or consulting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such firm required to be made hereunder.

The firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to Officer and the Company within fifteen (15) calendar days after the date on which Officer's right to a Payment is triggered (if requested at that time by Officer or the Company) or such other time as requested by Officer or the Company. If the firm determines that no Excise Tax is payable with respect to a Payment, either before or after the application of the Reduced Amount, it shall furnish Officer and the Company with an opinion reasonably acceptable to Officer that no Excise Tax will be imposed with respect to such Payment. Any good faith determinations of the firm made hereunder shall be final, binding and conclusive upon Officer and the Company.

5. COMPANY PROPERTY.

All documents, records, apparatus, equipment and other physical property that is furnished to or obtained by Officer in the course of his employment with the Company shall be and remain the sole property of the Company. Officer agrees that, upon the termination of his employment, as a condition of receiving benefits under this Agreement, he shall return all such property (whether or not it pertains to "*Confidential Information*" as defined in the Officer's Confidentiality and Inventions Agreement with the Company), and agrees not to make or retain copies, reproductions or summaries of any such property.

6. OTHER TERMINATIONS.

Notwithstanding anything to the contrary set forth herein, the Officer is not eligible for severance benefits under this Agreement if (i) the Officer is terminated within thirty (30) days following the Officer's refusal to accept an offer of comparable employment by any successor to the Company or an affiliate thereof (provided that "comparable employment" shall mean employment with job responsibilities not violative of Section 2.5(i), base salary in an amount not violative of Section 2.5(iii), and at a business office the location of which is not violative of Section 2.5(ii)); (ii) the Officer terminates employment in order to accept employment with another entity that is wholly or partly owned (directly or indirectly) by the Company or an affiliate, (iii) the Officer does not satisfy the conditions for receipt of benefits as set forth in Sections 3.4 and 5 of this Agreement; or (iv) the Officer's employment terminates due to death, disability or any other reason other than a Covered Termination.

7. ACKNOWLEDGEMENT.

Officer hereby acknowledges that Officer has consulted with or has had the opportunity to consult with independent counsel of Officer's own choice concerning this Agreement, and has been advised to do so by the Company, and Officer has read and understands this Agreement, is fully aware of its legal effect, and has entered into it freely based on Officer's own judgment.

8. GENERAL.

This Agreement is made in San Diego, California. This Agreement shall be construed and interpreted in accordance with the internal laws of the State of California. This Agreement supersedes and replaces any other agreement between Officer and the Company regarding severance benefits and/or compensation upon termination of employment, and cannot be amended or modified except by written agreement between Officer and the Company. This Agreement may be executed in two counterparts, each of which shall be deemed an original, all of which together shall constitute one and the same instrument.

6.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first above written.

**SOPHIRIS BIO
INC.**

By: /s/ Lars Ekman
Name: Lars
Ekman
Title:
Chairman of
the Board

Accepted and agreed:

/s/ Randall E. Woods
Randall E. Woods

7.

EXHIBIT A

RELEASE AND WAIVER OF CLAIMS

In consideration of the payments and other benefits set forth in the Officer Change in Control Severance Benefit Agreement dated _____ to which this form is attached, I, Randall E. Woods, hereby furnish Sophiris Bio Inc. (the "*Company*"), with the following release and waiver ("*Release and Waiver*").

In exchange for the consideration provided to me by the Change in Control Severance Benefit Agreement that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, Affiliates, and assigns from any and all claims, liabilities and obligations (excluding indemnification obligations and rights under the Company's directors and officers insurance policies) both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to my signing this Release and Waiver. This general release includes, but is not limited to: (1) all claims arising out of or in any way related to my employment with the Company or the termination of that employment; (2) all claims related to my compensation or benefits from the Company, including, but not limited to, salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership interests in the Company; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including, but not limited to, claims for fraud, defamation, emotional distress, and discharge in violation of public policy; (5) all federal, state, and local statutory claims, including, but not limited to, claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) ("*ADEA*"), and the California Fair Employment and Housing Act (as amended).

I also acknowledge that I have read and understand Section 1542 of the California Civil Code which reads as follows: "A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor." I hereby expressly waive and relinquish all rights and benefits under that section and any law of any jurisdiction of similar effect with respect to any claims I may have against the Company.

I acknowledge that, among other rights, I am knowingly and voluntarily waiving and releasing any rights I may have under ADEA. I also acknowledge that the consideration given for this Release and Waiver is in addition to anything of value to which I was already entitled as an employee of the Company. If I am 40 years of age or older upon execution of this Release and Waiver, I further acknowledge that I have been advised by this writing, as required by the Older Workers Benefit Protection Act, that: (A) my release and waiver granted herein does not relate to claims under the ADEA that may arise after the date I execute this Release and Waiver; (B) I should consult with an attorney prior to executing this Release and Waiver (although I may choose voluntarily not to do so), (C) I have twenty-one

(21) days to consider this Release and Waiver (although I may choose to voluntarily execute this Release and Waiver earlier); (D) I have seven (7) days following the execution of this Release and Waiver to revoke the Release and Waiver; and (E) this Release and Waiver shall not be effective until the seven (7) day revocation period has expired unexercised.

If I am less than 40 years of age upon execution of this Release and Waiver, I acknowledge that I have the right to consult with an attorney prior to executing this Release and Waiver (although I may choose voluntarily not to do so); and I have five (5) days from the date of termination of my employment with the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier).

I acknowledge my continuing obligations under my Confidentiality and Inventions Assignment Agreement (“**Confidentiality and Inventions Agreement**”), which is attached hereto. Pursuant to my Confidentiality and Inventions Agreement I understand that among other things, I must not use or disclose any confidential or proprietary information of the Company and I must immediately return all Company property and documents (including all embodiments of proprietary information) and all copies thereof in my possession or control. I understand and agree that my right to the severance benefits I am receiving in exchange for my agreement to the terms of this Release and Waiver is contingent upon my continued compliance with my Confidentiality and Inventions Agreement.

8.

This Release and Waiver, including the Confidentiality and Inventions Agreement attached hereto, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company that is not expressly stated herein. This Release and Waiver may only be modified by a writing signed by both me and a duly authorized officer of the Company.

Date:

By:

9.

Exhibit 10.2

OFFICER CHANGE IN CONTROL SEVERANCE BENEFIT AGREEMENT

This **OFFICER CHANGE IN CONTROL SEVERANCE BENEFIT AGREEMENT** (the “*Agreement*”) is made and entered into effective as of September 9, 2014, (the “*Effective Date*”), by and between Sophiris Bio Inc., a British Columbia, Canada corporation (the “*Company*”), and Allison Hulme (the “*Officer*”). The Company and the Officer are hereinafter collectively referred to as the “Parties”, and individually referred to as a “Party”.

RECITALS

WHEREAS, the Company desires to continue to employ Officer to provide personal services to the Company in that capacity, and wishes to provide Officer with certain severance benefits in return for Officer’s services, and Officer wishes to be so employed and to receive such benefits; and

WHEREAS, the Company and Officer wish to enter into this Agreement to define their mutual rights and duties with respect to Officer’s severance benefits;

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, and for other good and valuable consideration, the Parties, intending to be legally bound, agree as follows:

AGREEMENT

1. EMPLOYMENT.

1.1 Loyalty; At Will Employment. During the Officer’s employment by the Company, the Officer shall devote Officer’s full business energies, interest, abilities and productive time to the proper and efficient performance of Officer’s duties as an employee of the Company unless otherwise approved in writing by the Officer’s supervisor. Officer’s employment with the Company is at will and not for any specified period and may be terminated at any time, with or without Cause, by either Officer or Company, subject to the provisions of Sections 3 and 4 below.

1.2 Termination of Obligations. In the event of the termination of the Officer's employment with the Company, the Company shall have no obligation to pay Officer any base salary, bonus or other compensation or benefits, except as earned prior to the date of termination or as provided in Section 3 or for benefits due to the Officer (and/or the Officer's dependents) under the terms of the Company's benefit plans. To the extent permitted by applicable laws, the Company may offset any amounts Officer owes it or its subsidiaries against any amount it owes Officer pursuant to Section 3.

1.3 Term. The term of this Agreement shall begin on the Effective Date and shall continue until Officer's employment with the Company is terminated for any reason.

2. DEFINITIONS.

For purposes of this Agreement, the following terms shall have the following meanings:

2.1 Board. "*Board*" means the Board of Directors of the Company.

2.2 Cause. "*Cause*" for the Company to terminate Officer's employment shall mean::

- (i) Officer's repeated failure to satisfactorily perform his or her job duties, including but not limited to Officer's refusal or failure to follow lawful and reasonable directions of the supervisor to whom Officer reports;
- (ii) Officer's commission of an act that materially injures the business of the Company;
- (iii) Officer's commission of an act constituting dishonesty, fraud, or immoral or disreputable conduct;

1.

- (iv) Officer's conviction of a felony, or conviction of any crime involving moral turpitude;

- (v) Officer's engaging or in any manner participating in any activity which is directly competitive with or injurious to the Company, or which violates any material provisions of this Agreement or any written agreement with the Company; or

- (vi) Officer's use or intentional appropriation for Officer's personal use or benefit of any funds, information or properties of the Company not authorized by the Company to be so used or appropriated.

The determination that the termination is for Cause shall be made by the Board in its sole discretion.

2.3 Change in Control. For purposes of this Agreement, "*Change in Control*" means:

- (i) an acquisition by any person, entity or group within the meaning of Section 13(d) or 14(d) of the Exchange Act, or any comparable successor provisions (excluding any employee benefit plan, or related trust, sponsored or maintained by the Company or subsidiary of the Company or other entity controlled by the Company) of the beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act, or comparable successor rule) of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur solely because the level of ownership held by a person, entity or group exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, a person, entity or group becomes the owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities owned by such person, entity or group over the designated percentage threshold, then a Change in Control shall be deemed to occur;

- (ii) there is consummated a merger, consolidation, plan of arrangement or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation, plan of arrangement or similar transaction, the stockholders of the Company immediately prior thereto do not own, directly or indirectly, outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving entity in such merger, consolidation, plan of arrangement or similar transaction or more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation, plan of arrangement or similar transaction; or

(iii) there is consummated a sale or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportions as their ownership of the Company immediately prior to such sale, lease, license or other disposition.

2.4 Covered Period. “*Covered Period*” means the period commencing one (1) month immediately prior to a Change in Control of the Company and ending eighteen (18) months immediately following a Change in Control of the Company.

2.5 Covered Termination. “*Covered Termination*” means a termination without Cause or resignation for Good Reason that occurs within the Covered Period. For such purposes, if the events giving rise to the Officer’s right to resign for Good Reason arise within the Covered Period, and the Officer’s resignation occurs not later than thirty (30) days after the expiration of the Cure Period (as defined below), such termination shall be a Covered Termination.

2.6 Good Reason. “*Good Reason*” for Officer to resign employment shall mean the occurrence of any of the following events without Officer’s written consent:

(i) a material reduction in Officer’s duties, authority, or responsibilities relative to the duties, authority, or responsibilities in effect immediately prior to such reduction;

(ii) the relocation of Officer’s principle place of employment resulting in an increase in Officer’s one-way commuting distance from his or her residence by at least forty (40) miles; and

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(iii) a material reduction by the Company of Officer's base salary, by more than ten percent (10%) (unless such reduction is made pursuant to an across the board reduction generally applicable to senior executives of the Company);

provided, however, that such termination by Officer shall only be deemed for Good Reason pursuant to the foregoing definition if (i) the Company is given written notice from Officer within thirty (30) days following the first occurrence of the condition that he or she considers to constitute Good Reason, describing the condition, and the Company fails to satisfactorily remedy such condition within thirty (30) days following such written notice (the "**Cure Period**"), and (ii) Officer resigns employment and service from all positions Officer holds with the Company effective no later than thirty (30) days following the end of the Cure Period.

2.7 Integration. The parties acknowledge that the definition of "for Cause" contained within this Agreement may differ from the definitions of "for Cause" contained within Officer's stock option agreement or other equity award agreements. The Parties agree that unless it is determined that Officer shall be terminated for "Cause" as defined in this Agreement, there shall be no termination for "Cause" under any of Officer's stock option agreements or other equity award agreements. Therefore, unless otherwise expressly provided in such equity award agreement, the definition of "Cause" in this Agreement shall supersede and replace in its entirety any definition of "Cause" that may be included in Officer's equity award agreements.

3. COMPENSATION UPON TERMINATION.

3.1 Death or Disability. If the Officer's employment with the Company is terminated as a result of death or disability, the Company shall pay to Officer, and/or Officer's heirs, the Officer's base salary and accrued and unused vacation benefits earned through the date of termination at the rate in effect at the time of termination, less standard deductions and withholdings, and the Company shall thereafter have no further obligations to the Officer and/or Officer's heirs under this Agreement.

3.2 With Cause or Without Good Reason. If the Officer's employment with the Company is terminated by the Company for Cause or if the Officer terminates employment with the Company without Good Reason, the Company shall pay the Officer's base salary and accrued and unused vacation benefits earned through the date of termination at the rate in effect at the time of termination, less standard deductions and withholdings, and the Company shall thereafter have no further obligations to the Officer under this Agreement.

3.3 Without Cause or for Good Reason Termination Outside of Covered Period. In the event Officer's employment with the Company is terminated by the Company without Cause or Officer resigns for Good Reason in each case at any time other than during the Covered Period, the Company shall pay the Officer's base salary and

accrued and unused vacation benefits earned through the date of termination at the rate in effect at the time of termination, less standard deductions and withholdings, and the Company shall thereafter have no further obligations to the Officer under this Agreement.

3.4 Change in Control Related Severance Benefits. In the event that Officer's employment with the Company is terminated in a Covered Termination, and Officer signs the Release and Waiver of Claims as set forth as Exhibit A or such other form of release as the Company may require in order to comply with applicable laws (the "**Release**") on or within the time period set forth therein, but in no event later than forty-five (45) days after Officer's termination date, and allows such Release to become effective in accordance with its terms, then Officer will receive the following benefits:

3.5 the equivalent of eighteen (18) months of the Officer's Base Salary (as defined below), less standard deductions and withholdings, which shall be paid in a single lump sum within five (5) days after the effective date of the Release or if later, the effective date of the Change in Control (if Officer's termination occurs prior to the Change in Control). "**Base Salary**" shall mean Officer's base pay (excluding incentive pay, premium pay, commissions, overtime, bonuses and other forms of variable compensation), at the rate in effect during the last regularly scheduled payroll period immediately preceding the date of the termination, but prior to any reduction that would give rise to the Officer's right to resign for Good Reason.

(i) If Officer is eligible for and timely elects continued group health plan coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("**COBRA**") following Officer's termination, the Company will pay the Officer's COBRA group health insurance premiums for the Officer and his eligible dependents for a period of eighteen (18) months following the effective date of the Release or if later, the effective date of the Change in Control (if Officer's termination occurs prior to the Change in Control). (the "**COBRA Payment Period**"); provided, however, that any such payments will cease (or will not commence) if Officer voluntarily enrolls in a health insurance plan offered by another employer or entity during the period in which the Company is paying such premiums or if Officer becomes ineligible for COBRA coverage prior to or during such period. Officer is required to immediately notify the Company in writing of any such enrollment in a plan offered by another employer. For purposes of this Section 3.4(ii), references to COBRA premiums shall not include any amounts payable by Officer under an Internal Revenue Code Section 125 health care reimbursement plan.

3.

Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Officer a taxable cash amount, which payment shall be made regardless of whether Officer or Officer's eligible family members elect health care continuation coverage (the "**Health Care Benefit Payment**"). The Health Care Benefit Payment shall be paid in monthly installments on the same schedule that the COBRA Premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company would have otherwise paid for COBRA insurance premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the earlier of (i) expiration of the COBRA Payment Period, or (ii) the date Officer voluntarily enrolls in a health insurance plan offered by another employer or entity.

(ii) The greater of 150% of: (A) Officer's last annual bonus amount that had been paid under the Company's current bonus plan or any successor bonus plan (the "**Bonus Plan**"), or (B) the last annual target bonus amount that was in effect under the provisions of the Bonus Plan preceding Officer's termination date, (such greater amount is the "**Bonus Payment**"). The Bonus Payment shall be subject to all standard deductions and withholdings and shall be paid in a single lump sum within five (5) days after the later of (A) the effective date of the Release, or (B) the effective date of the Change in Control (if Officer's termination occurs prior to the Change in Control); and

(iii) Full accelerated vesting of all unvested shares subject to any outstanding stock options, restricted stock or other equity awards then held by Officer that are subject to vesting solely upon the passage of time and the Officer's continued services, such that all shares shall be vested and fully exercisable as of the effective date of the Release, or if later, the effective date of the Change in Control (if Officer's termination occurs prior to the Change in Control). In order to give effect to the foregoing provision, notwithstanding anything to the contrary set forth in Officer's equity award agreements that may provide for immediate forfeiture of unvested equity awards in connection with a termination of employment or a limited post-termination exercise period for vested options, following any termination of Officer's employment that is without Cause or for Good Reason and thus may potentially qualify as a Covered Termination if a Change in Control occurs within the one (1) month period thereafter, none of Officer's equity awards shall terminate with respect to any vested or unvested portion subject to such award before the later of (A) one (1) month following such termination, or (B) the effective date of the Release; provided, however, that such awards may still earlier terminate upon a Change in Control to the extent the awards will not be assumed, continued or substituted by the acquiring or continuing entity.

4. TAX COMPLIANCE.

4.1 Application of Internal Revenue Code Section 409A. Notwithstanding anything to the contrary herein, the following provisions apply to the extent severance benefits provided herein are subject to Section 409A of the Internal Revenue Code of 1986, as amended (the "**Code**") and the regulations and other guidance thereunder and any state law of similar effect (collectively "**Section 409A**"). Severance benefits shall not commence until Officer has a "separation from service" for purposes of Section 409A. Each installment of severance benefits is a separate "payment" for purposes of Treas. Reg. Section 1.409A-2(b)(2)(i), and to the maximum extent such exemptions are available, the severance

benefits are intended to satisfy the exemptions from application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, to the extent such exemptions are not available and Officer is, upon separation from service, a “specified employee” for purposes of Section 409A, then, solely to the extent necessary to avoid adverse personal tax consequences under Section 409A, the timing of the severance benefits payments shall be delayed until the earlier of (i) six (6) months and one day after Officer’s separation from service, or (ii) Officer’s death. The severance benefits are intended to qualify for an exemption from application of Section 409A or comply with its requirements to the extent necessary to avoid adverse personal tax consequences under Section 409A, and any ambiguities herein shall be interpreted accordingly.

4.2 Parachute Payment. If any payment or benefit Officer would receive pursuant to a Change in Control or otherwise (“*Payment*”) would (i) constitute a “parachute payment” within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “*Excise Tax*”), then such Payment shall be reduced to the Reduced Amount. The “*Reduced Amount*” shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Officer’s receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting “parachute payments” is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for Officer. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

4.

In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, Officer agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, Officer will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

The Company shall engage a nationally recognized accounting or consulting firm to perform the foregoing calculations. If the firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, then the Company shall appoint another nationally recognized accounting or consulting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such firm required to be made hereunder.

The firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to Officer and the Company within fifteen (15) calendar days after the date on which Officer's right to a Payment is triggered (if requested at that time by Officer or the Company) or such other time as requested by Officer or the Company. If the firm determines that no Excise Tax is payable with respect to a Payment, either before or after the application of the Reduced Amount, it shall furnish Officer and the Company with an opinion reasonably acceptable to Officer that no Excise Tax will be imposed with respect to such Payment. Any good faith determinations of the firm made hereunder shall be final, binding and conclusive upon Officer and the Company.

5. COMPANY PROPERTY.

All documents, records, apparatus, equipment and other physical property that is furnished to or obtained by Officer in the course of his employment with the Company shall be and remain the sole property of the Company. Officer agrees that, upon the termination of his employment, as a condition of receiving benefits under this Agreement, he shall return all such property (whether or not it pertains to "*Confidential Information*" as defined in the Officer's Confidentiality and Inventions Agreement with the Company), and agrees not to make or retain copies, reproductions or summaries of any such property.

6. OTHER TERMINATIONS.

Notwithstanding anything to the contrary set forth herein, the Officer is not eligible for severance benefits under this Agreement if (i) the Officer is terminated within thirty (30) days following the Officer's refusal to accept an offer of comparable employment by any successor to the Company or an affiliate thereof (provided that "comparable employment" shall mean employment with job responsibilities not violative of Section 2.6(i), base salary in an amount

not violative of Section 2.6(iii), and at a business office the location of which is not violative of Section 2.6(ii)); (ii) the Officer terminates employment in order to accept employment with another entity that is wholly or partly owned (directly or indirectly) by the Company or an affiliate, (iii) the Officer does not satisfy the conditions for receipt of benefits as set forth in Sections 3.4 and 5 of this Agreement; or (iv) the Officer's employment terminates due to death, disability or any other reason other than a Covered Termination.

7. ACKNOWLEDGEMENT.

Officer hereby acknowledges that Officer has consulted with or has had the opportunity to consult with independent counsel of Officer's own choice concerning this Agreement, and has been advised to do so by the Company, and Officer has read and understands this Agreement, is fully aware of its legal effect, and has entered into it freely based on Officer's own judgment.

8. GENERAL.

This Agreement is made in San Diego, California. This Agreement shall be construed and interpreted in accordance with the internal laws of the State of California. This Agreement supersedes and replaces any other agreement between Officer and the Company regarding severance benefits and/or compensation upon termination of employment, and cannot be amended or modified except by written agreement between Officer and the Company. This Agreement may be executed in two counterparts, each of which shall be deemed an original, all of which together shall contribute one and the same instrument.

5.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first above written.

SOPHIRIS BIO INC.

By: /s/ Randall E. Woods
Name: Randall E.
Woods
Title: President and
Chief Executive
Officer

Accepted and agreed:

/s/ Allison Hulme
Allison Hulme

6.

EXHIBIT A

RELEASE AND WAIVER OF CLAIMS

In consideration of the payments and other benefits set forth in the Officer Change in Control Severance Benefit Agreement dated _____ to which this form is attached, I, _____, hereby furnish Sophiris Bio Inc. (the "*Company*"), with the following release and waiver ("*Release and Waiver*").

In exchange for the consideration provided to me by the Change in Control Severance Benefit Agreement that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, Affiliates, and assigns from any and all claims, liabilities and obligations (excluding indemnification obligations and rights under the Company's directors and officers insurance policies) both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to my signing this Release and Waiver. This general release includes, but is not limited to: (1) all claims arising out of or in any way related to my employment with the Company or the termination of that employment; (2) all claims related to my compensation or benefits from the Company, including, but not limited to, salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership interests in the Company; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including, but not limited to, claims for fraud, defamation, emotional distress, and discharge in violation of public policy; (5) all federal, state, and local statutory claims, including, but not limited to, claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) ("*ADEA*"), and the California Fair Employment and Housing Act (as amended).

I also acknowledge that I have read and understand Section 1542 of the California Civil Code which reads as follows: "A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor." I hereby expressly waive and relinquish all rights and benefits under that section and any law of any jurisdiction of similar effect with respect to any claims I may have against the Company.

I acknowledge that, among other rights, I am knowingly and voluntarily waiving and releasing any rights I may have under ADEA. I also acknowledge that the consideration given for this Release and Waiver is in addition to anything of value to which I was already entitled as an employee of the Company. If I am 40 years of age or older upon execution of this Release and Waiver, I further acknowledge that I have been advised by this writing, as required by the Older Workers Benefit Protection Act, that: (A) my release and waiver granted herein does not relate to claims under the ADEA that may arise after the date I execute this Release and Waiver; (B) I should consult with an attorney prior to executing this Release and Waiver (although I may choose voluntarily not to do so), (C) I have twenty-one

(21) days to consider this Release and Waiver (although I may choose to voluntarily execute this Release and Waiver earlier); (D) I have seven (7) days following the execution of this Release and Waiver to revoke the Release and Waiver; and (E) this Release and Waiver shall not be effective until the seven (7) day revocation period has expired unexercised.

If I am less than 40 years of age upon execution of this Release and Waiver, I acknowledge that I have the right to consult with an attorney prior to executing this Release and Waiver (although I may choose voluntarily not to do so); and I have five (5) days from the date of termination of my employment with the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier).

I acknowledge my continuing obligations under my Confidentiality and Inventions Assignment Agreement (“**Confidentiality and Inventions Agreement**”), which is attached hereto. Pursuant to my Confidentiality and Inventions Agreement I understand that among other things, I must not use or disclose any confidential or proprietary information of the Company and I must immediately return all Company property and documents (including all embodiments of proprietary information) and all copies thereof in my possession or control. I understand and agree that my right to the severance benefits I am receiving in exchange for my agreement to the terms of this Release and Waiver is contingent upon my continued compliance with my Confidentiality and Inventions Agreement.

This Release and Waiver, including the Confidentiality and Inventions Agreement attached hereto, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company that is not expressly stated herein. This Release and Waiver may only be modified by a writing signed by both me and a duly authorized officer of the Company.

Date:

By:

7.

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Randall E. Woods, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sophiris Bio Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a.) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

 - b.) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c.) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a.) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b.) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Randall E. Woods
Randall E. Woods
President & Chief Executive Officer

Date: November 12, 2014

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Peter T. Slover, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sophiris Bio Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a.) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

 - b.) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c.) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a.) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b.) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Peter T. Slover
Peter T. Slover
Chief Financial Officer

Date: November 12, 2014

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of Sophiris Bio Inc. (the Company) for the quarter ended September 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Randall E. Woods, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Randall E. Woods
Randall E. Woods
President & Chief Executive Officer

Date: November 12, 2014

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of Sophiris Bio Inc. (the Company) for the quarter ended September 30, 2014, as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Peter T. Slover, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Peter T. Slover
Peter T. Slover
Chief Financial Officer

Date: November 12, 2014

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.