SOPHIRIS BIO INC.

FORM 10-Q
(Quarterly Report)

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Industry	Pharmaceuticals
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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 JUNE 30 , 201 7

☐ **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	**98-1008712**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1258 Prospect Street, La Jolla, California	**92037**
(Address of Principal Executive Offices)	(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, smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth 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	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the exte nded transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

As of August 1, 2017, the registrant had 30,111,153 common shares (no par value) outstanding.

SOPHIRIS BIO INC.
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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Sophiris Bio Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share amounts)
(Unaudited)

	June 30 , 201 7	December 31, 201 6
Assets:		
Current assets:		
Cash and cash equivalents	$ 6,824	$ 12,800
Securities available-for-sale	17,205	16,201
Other receivables	69	128
Prepaid expenses	948	846
Total current assets	25,046	29,975
Property and equipment, net	2	4
Other long-term assets	—	19
Total assets	$ 25,048	$ 29,998
Liabilities and shareholders ' equity:		
Current liabilities:		
Accounts payable	$ 506	$ 459
Accrued expenses	1,154	1,762
Total current liabilities	1,660	2,221
Warrant liability	10,162	13,396
Stock-based compensation liability	—	57
Total liabilities	11,822	15,674
Commitments and contingencies		
Shareholders ' equity:		
Common shares, unlimited authorized shares, no par value; 30,111,153 and 30,107,644 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	131,246	131,245
Contributed surplus	24,824	23,900
Accumulated other comprehensive gain	85	99
Accumulated deficit	(142,929)	(140,920)
Total shareholders ' equity	13,226	14,324
Total liabilities and shareholders ' equity	$ 25,048	$ 29,998

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	201 7	201 6	2017	2016
Operating expenses:				
Research and development	$ 1,387	$ 978	$ 2,595	$ 1,907
General and administrative	1,367	1,357	2,736	2,521
Total operating expenses	2,754	2,335	5,331	4,428
Other income (expense):				
Interest expense	—	(137)	—	(287)
Interest income	53	3	103	7
Gain (l oss) on revaluation of warrant liability	3,320	(1,619)	3,234	(1,619)
Other expense, net	(9)	(3)	(16)	(7)
Total other income (expense)	3,364	(1,756)	3,321	(1,906)
Net income (loss)	$ 610	$ (4,091)	$ (2,010)	$ (6,334)
Basic income (loss) per share	$ 0.02	$ (0.21)	$ (0.07)	$ (0.35)
Dil uted income (loss) per share	$ 0.02	$ (0.21)	$ (0.07)	$ (0.35)
Weighted average number of outstanding shares – basic	30,111	19,340	30,111	18,292
Weighted average number of outstanding shares – diluted	30,515	19,340	30,111	18,292
Other comprehensive income (loss):				
Unrealized loss on securities available-for-sale	(1)	—	(14)	—
Total other comprehensive income (loss)	$ 609	$ (4,091)	$ (2,024)	$ (6,334)

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

Sophiris Bio Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended June 30 ,	
	201 7	**201 6**
Cash flows used in operating activities		
Net loss for the period	$ (2,010)	$ (6,334)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	867	185
Amortization of debt discount	—	62
Depreciation of property and equipment	3	9
Amortization of discount on securities available-for-sale	92	—
Change in fair value warrant liability	(3,234)	1,619
Foreign exchange transaction loss	4	1
Changes in operating assets and liabilities:		
Other receivables	59	7
Prepaid expenses and other long-term assets	(83)	316
Accounts payable	41	(707)
Accrued expenses	(608)	107
Net cash used in operating activities	(4,869)	(4,735)
Cash flows (used in) provided by investing activities		
Purchase of property and equipment	(1)	—
Maturities of securities available-for-sale	4,291	2,750
Purchases of securities available-for-sale	(5,400)	(250)
Net cash (used in) provided by investing activities	(1,110)	2,500
Cash flows provided by financing activities		
Proceeds from exercise of stock options	2	3
Proceeds from the issuance of financing, net of paid offering costs	—	4,770
Proceeds from the exercise of warrants	—	840
Principal payments on promissory notes	—	(921)
Net cash provided by financing activities	2	4,692
Effect of exchange rate changes on cash and cash equivalents	1	—
Net (decrease) increase cash and cash equivalents	(5,976)	2,457
Cash and cash equivalents at beginning of period	12,800	5,881
Cash and cash equivalents at end of period	$ 6,824	$ 8,338
Supplemental disclosures of non-cash investing and financing activities:		
Change in the fair value of stock-based compensation liability recorded to contributed surplus	$ (57)	$ (66)
Valuation of warrant liability upon issuance of warrants	$ —	$ 1,687
Valuation of exercised warrants reclassified from warrant liability to contributed surplus	$ —	$ 1,048
Issuance costs included in accrued expenses but not paid	$ —	$ 60

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

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 topsalysin for treatment of the symptoms of clinically significant localized prostate cancer and benign prostatic hyperplasia, or BPH, commonly referred to as an enlarged prostate. The Company is governed by the British Columbia Business Corporations Act. 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.

The condensed consolidated financial statements include the accounts of Sophiris Bio Inc. and its wholly-owned subsidiaries, Sophiris Bio Corp. and Sophiris Bio Holding Corp., both of which are incorporated in the State of Delaware.

2. 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 on March 27, 2017. The accompanying 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.

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 stock-based compensation expense, fair value of the warrant liability 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

Historically gains and losses resulting from foreign currency translation were 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 expense.

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 and declines in value judged to be other-than-temporary 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 June 30, 2017 and December 31, 2016. 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.

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.

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 to clinical research organizations in connection with clinical studies;
- fees to investigative sites in connection with clinical studies;
- fees to vendors in connection with preclinical development activities;
- fees to vendors associated with the development of companion diagnostics; and
- fees 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 consultants of the Company, 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 Accounting Standards Codification, or ASC, Topic 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 zero at June 30, 2017. As the calculated fair value of the stock options at June 30, 2017 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 was recorded as an adjustment to Contributed Surplus of ($23,000) and ($57,000) for the three and six months ended June 30, 2017, respectively, and ($19,000) and ($66,000) for the three and six months ended June 30, 2016, respectively.

Warrant Liability

In connection with the offerings the Company completed in 2016, the Company issued warrants to purchase common shares. These warrants may require the Company to pay the warrant holder cash under certain provisions of the warrant and therefore the Company is accounting for these warrants as a liability in accordance with ASC 480 *"Distinguishing Liabilities from Equity"* . As a result of these warrants being classified as liabilities, the Company is required to calculate the fair value of these warrants at each reporting date. The fair value of these warrants are calculated utilizing a Black-Scholes pricing model. The Company calculated the initial fair value of these warrants at the date the warrants were issued. At each reporting date the Company is required to remeasure the fair value of the warrant liability and any corresponding increase or decrease to the warrant liability is recorded as a component of other income or expense in its consolidated statement of operations and comprehensive loss. In addition, if a warrant holder exercises warrants the Company is required to revalue the fair value of the underlying warrants on the date of exercise and reclassify the change in the fair value from the warrant liability to contributed surplus.

Certain inputs utilized in the Company's Black-Scholes fair value calculation may fluctuate in future periods based upon factors which are outside of the Company's control. A significant change in one or more of these inputs used in the calculation of the fair value may cause a significant change to the fair value of the Company's warrant liability which could also result in material non-cash gain or loss being reported in the Company's consolidated statement of operations and comprehensive loss.

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 Financial Accounting Standards Board, or FASB, issued new guidance related to revenue recognition (Accounting Standards Update, or ASU, No. 2014-09 Revenue from Contracts with Customers (Topic 606)). Subsequently the FASB has issued additional guidance (ASU Nos. 2015-14; 2016-08; 2016-10; 2016-12; 2016-20 Revenue from Contracts with Customers (Topic 606)). The guidance establishes principles for reporting information about the nature, amount, timing, and uncertainty of revenue and cash flows arising from an entity's contracts with customers. The guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Two methods of adoption are permitted: (a) full retrospective adoption, meaning the standard is applied to all periods presented or (b) modified retrospective adoption, meaning the cumulative effect of applying the new guidance is recognized as an adjustment to the opening retained earnings balance. The Company does not intend to adopt the new guidance early and is in the process of determining the adoption method. The Company did not recognize any revenue from contracts with customers in the years ended December 31, 2016, 2015 and 2014. Although the Company is still evaluating the impact of the new standard, the Company anticipates that the impact will not be material to the consolidated financial statements as the Company does not currently generate revenues from contracts with customers.

In February 2016, the FASB issued ASU No. 2016-02, " *Lease* s *(Topic 842)* ". This guidance requires lessees to recognize a lease liability and a right-of-use asset with the exception of short-term leases. In addition, lessees are required to classify leases as either operating or finance based on current criteria of whether or not the lease is effectively a financed purchase by the lessee. The new standard is effective for the annual reporting period beginning after December 15, 2018 and early adoption is permitted. Although the Company is in the process of evaluating the impact of this guidance on its consolidated financial statements and related disclosures, the Company expects that its operating lease will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon adoption.

In August 2016, the FASB issued ASU 2016-15, " *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments",* addressing eight specific cash flow issues in an effort to reduce diversity in practice. The amended guidance is effective for fiscal years beginning after December 31, 2017, and for interim periods within those years. Early adoption is permitted. The Company is in the process of evaluating the impact of this guidance on its consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, " *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting"* . The new standard provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The new standard will be effective for the Company on January 1, 2018; however, early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company's financial position or results of operations.

3. Net income (loss) per common share

Basic net income (loss) per share is calculated by dividing the net income (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 income (loss) per share is computed by dividing the net income (loss) attributable to common shareholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method.

The following table sets forth the computation of basic and diluted EPS (in thousands, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Basic net income (loss) per share				
Net income (loss) allocated to common stockholders	$ 610	$ (4,091)	$ (2,010)	$ (6,334)
Weighted average common shares outstanding-basic	30,111	19,340	30,111	18,292
Net income (loss) per share-basic	$ 0.02	$ (0.21)	$ (0.07)	$ (0.35)
Diluted n et income (loss) per share				
Net income (loss) allocated to common stockholders -diluted	$ 603	$ (4,091)	$ (2,010)	$ (6,334)
Weighted average common shares outstanding-basic	30,111	19,340	30,111	18,292
Dilutive securities	404	—	—	—
Weighted average common shares outstanding-dilutive	30,515	19,340	30,111	18,292
Net income (loss) per share-diluted	$ 0.02	$ (0.21)	$ (0.07)	$ (0.35)

The following diluted securities were excluded from the calculation of the denominator for diluted net income per common share for the three and six months ended June 30, 2017 and 2016 due to their antidilutive effects.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Options to purchase common shares	2,497	2,014	2,888	2,014
Common share purchase warrants	5,712	1,776	5,725	1,776

4. Securities Available-for-Sale

Securities available-for-sale consisted of the following as of June 30, 2017 (in thousands):

	June 30 , 201 7			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Commercial paper	$ 3,645	$ —	$ —	$ 3,645
U.S. government sponsored enterprise securities	13,574	—	(14)	13,560
	$ 17,219	$ —	$ (14)	$ 17,205

The amortized cost and estimated fair value of the Company securities available-for-sale by contractual maturity as of June 30, 2017 are shown below (in thousands):

	June 30 , 201 7			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Within one year	$ 17,219	$ —	$ (14)	$ 17,205
After one year	—	—	—	—
	$ 17,219	$ —	$ (14)	$ 17,205

Securities available-for-sale consisted of the following as of December 31, 2016 (in thousands):

	December 31, 201 6			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Commercial paper	$ 3,890	$ —	$ —	$ 3,890
U.S. government sponsored enterprise securities	12,311	—	—	12,311
	$ 16,201	$ —	$ —	$ 16,201

The amortized cost and estimated fair value of the Company securities available-for-sale by contractual maturity as of December 31, 2016 are shown below (in thousands):

	December 31, 201 6			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Within one year	$ 16,201	$ —	$ —	$ 16,201
After one year	—	—	—	—
	$ 16,201	$ —	$ —	$ 16,201

5. Fair value measurement and financial instruments

As of June 30, 2017 the Company had $23.5 million of securities consisting of money market funds, commercial paper, and U.S. government sponsored enterprise securities with maturities that range from seven days to seven months with an overall average time to maturity of approximately three 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):

	June 30 , 201 7	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 5	$ 5	$ —	$ —
Commercial paper	9,968	—	9,968	—
U.S. government sponsored enterprise securities	13,560	—	13,560	—
Total assets	$ 23,533	$ 5	$ 23,528	$ —
Liabilities:				
Warrant liability	$ 10,162	$ —	$ —	$ 10,162
Stock based compensation liability	—	—	—	—
Total liabilities	$ 10,162	$ —	$ —	$ 10,162

	December 31, 201 6	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 57	$ 57	$ —	$ —
Commercial paper	16,085	—	16,085	—
U.S. government sponsored enterprise securities	12,311	—	12,311	—
Total assets	$ 28,453	$ 57	$ 28,396	$ —
Liabilities:				
Warrant liability	$ 13,396	$ —	$ —	$ 13,396
Stock-based compensation liability	57	—	—	57
Total liabilities	$ 13,453	$ —	$ —	$ 13,453

Warrant liability

In connection with the offering completed in May 2016, the Company issued 1,785,714 warrants to purchase its common shares. These warrants may require the Company to pay the warrant holder cash under certain provisions of the warrant and therefore the Company is accounting for these warrants as a liability. As a result of these warrants being classified as a liability, the Company is required to calculate their fair value at each reporting date. The fair value of these warrants is calculated utilizing a Black-Scholes pricing model. As of June 30, 2017, only 10,000 warrants remain outstanding from the May 2016 offering for which the fair value was remeasured as of June 30, 2017. The following inputs were utilized in the Black-Scholes pricing model:

	June 30, 2017	March 31, 2017	December 31 , 2016
Stock price	$ 2.20	$ 2.83	$ 2.80
Exercise price	$ 1.40	$ 1.40	$ 1.40
Risk-free interest rate	1.69%	1.73%	1.78%
Volatility	141.12%	147.06%	144.25%
Dividend yield	0.00%	0.00%	0.00%
Expected life in years	3.86	4.11	4.36
Calculated fair value per warrant	$ 1.92	$ 2.57	$ 2.55

In connection with the offering completed on August 2016, the Company issued 5,606,250 warrants to purchase its common shares. These warrants may require the Company to pay the warrant holder cash under certain provisions of the warrant and therefore the Company is accounting for these warrants as a liability. As a result of these warrants being classified as a liability, the Company is required to calculate the fair value of these warrants at each reporting date. The fair value of these warrants is calculated utilizing a Black-Scholes pricing model. The following inputs were utilized in the Black-Scholes pricing model:

	June 30, 2017	March 31, 2017	December 31 , 2016
Stock price	$ 2.20	$ 2.83	$ 2.80
Exercise price	$ 4.00	$ 4.00	$ 4.00
Risk-free interest rate	1.74%	1.80%	1.85%
Volatility	145.52%	143.07%	140.47%
Dividend yield	0.00%	0.00%	0.00%
Expected life in years	4.16	4.41	4.65
Calculated fair value per warrant	$ 1.81	$ 2.40	$ 2.38

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

	Six Months Ended June 30,	
	201 7	201 6
Balance at beginning of period	$ 13,396	$ —
Calculated fair value of the warrants on date of issuance	—	1,687
Fair value of warrants exercised recorded as an adjustment to contributed surplus	—	(1,048)
Change in fair value of warrant liability	(3,234)	1,619
Balance at end of period	$ 10,162	$ 2,258

Stock-based compensation liability

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:

	June 30, 2017	March 31, 2017	December 31, 2016
Stock price at the end of each reporting period	$ 2.20	$ 2.83	$ 2.80
Weighted average exercise price	$ 11.16	$ 11.14	$ 11.06
Risk-free interest rate	1.24%	1.03%	0.85%
Volatility	33.13%	80.71%	120.81%
Dividend yield	0.00%	0.00%	0.00%
Expected life in years	0.38	0.61	0.85
Calculated fair value per stock option	$ 0.00	$ 0.13	$ 0.33

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

	Six Months Ended June 30,	
	2017	2016
Balance at beginning of period	$ 57	$ 168
Change in fair value of stock-based compensation liability recorded as an adjustment to contributed surplus	(57)	(66)
Balance at end of period	$ —	$ 102

The Company recognizes transfers into and out of levels within the fair value hierarchy at the end of the reporting period in which the actual event or change in circumstances that caused the transfer occurs. There were no transfers of assets or liabilities between the fair value measurement classifications.

6. Prepaid expenses

Prepaid expenses as of June 30, 2017 and December 31, 2016 consisted of the following (in thousands):

	June 30, 2017	December 31, 2016
Prepaid insurance	$ 53	$ 273
Prepaid research and development expenses	779	546
Other prepaid expenses	116	27
Prepaid expenses	$ 948	$ 846

As of June 30, 2017 and December 31, 2016, prepaid research and development expenses included $0.7 million and $0.5 million, respectively, for upfront fees paid to our research and development organizations assisting with our on-going clinical trial and drug formulation and manufacturing. The upfront fees will be relieved in future periods based upon work completed.

7. Accrued expenses

Accrued expenses as of June 30, 2017 and December 31, 2016 consisted of the following (in thousands):

	June 30, 2017	December 31, 2016
Accrued personnel related costs	$ 547	$ 1,491
Accrued research and development expenses	315	87
Accrued audit and tax services	204	129
Other accrued expenses	88	55
Accrued expenses	$ 1,154	$ 1,762

8. Promissory notes

On September 2, 2016, the Company repaid the outstanding principal balance on its Loan and Security Agreement with Oxford Finance LLC, or Oxford. During the three and six months ended June 30, 2016, the Company paid interest expense of $0.1 million and $0.2 million on its loan with Oxford, respectively.

9 . Stock-based compensation plan

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. Prior to the Company's initial public offering, or IPO, the Company granted options to residents of the United States with an exercise price denominated in Canadian dollars subsequent to the Company's IPO, the Company issues its stock options with U.S. dollar denominated exercise prices.

As of June 30, 2017, the Company has 122,665 common shares which were available for issuance under the Plan.

The Company recognized stock-based compensation expense as follows for the three and six months ended June 30, 2017 and 2016 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	201 7	201 6	201 7	201 6
Research and development	$ 130	$ 37	$ 255	$ 69
General and administrative	335	58	612	116
Total	$ 465	$ 95	$ 867	$ 185

As of June 30, 2017 there was $1.5 million of total unrecognized compensation expense related to non-vested stock awards, which is expected to be recognized over a weighted average period of 1.2 years.

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
Outstanding at January 1, 201 7	2,868	$ 3.63
Options granted	85	2.45
Options exercised	(3)	0.4589
Options expired	(7)	24.40
Options forfeited	(55)	2.23
Outstanding at June 30, 2017	2,888	$ 3.58

The total amount of options outstanding at June 30, 2017 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.

The fair values of options granted during the six months ended June 30, 2017 and 2016 were estimated at the date of grant using the following weighted-average assumptions:

	Six Months Ended June 30,	
	201 7	201 6
Expected life of the option term (years)	4.1	3.8
Risk-free interest rate	1.61%	1.19%
Dividend rate	0%	0%
Volatility	144.8%	147.8%
Forfeiture rate	0.0%	3.4%

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, 201 6 included with our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 27 , 2017 . 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 June 30 , 2017 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 Capital Market. We are currently developing topsalysin (PRX302) as a treatment for clinically significant localized prostate cancer and as a treatment for the lower urinary tract symptoms of benign prostatic hyperplasia, or BPH, commonly referred to as an enlarged prostate. In 2004, we licensed exclusive rights to topsalysin from UVIC Industry Partnerships Inc., or UVIC, and The Johns Hopkins University, or Johns Hopkins, for the treatment of prostate cancer and in 2009, we licensed exclusive rights to topsalysin from UVIC and 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 topsalysin in Japan for the treatment of the symptoms of BPH, prostate cancer, prostatitis or other diseases of the prostate.

Topsalysin, a genetically modified recombinant protein, is delivered via ultrasound-guided injection directly into the prostate. This membrane-disrupting protein is selectively activated by enzymatically active prostate specific antigen, or PSA, which is only present in the prostate, leading to localized cell death and tissue disruption without damage to neighboring tissue and nerves. This method of administration limits the circulation of the drug in the body, and we believe that this limited systemic exposure to the drug, together with how the drug is activated in the prostate, greatly diminishes the risk of side effects.

W e have initiated a second Phase 2 clinical trial to confirm the dose and optimize the delivery of topsalysin for the treatment of clinically significant localized prostate cancer. We believe that the highly targeted mechanism by which topsalysin selectively destroys prostate tissue in BPH makes topsalysin a potential targeted focal treatment for localized prostate cancer. This study will utilize state of the art commercially available software which will allow us to use previously obtained MRI images of each patient's prostate and map the prostate image to a real time 3D ultrasound to target the delivery of topsalysin directly into and around the pre-identified clinically significant tumor. A clinically significant tumor is defined in our study as, either a Gleason score 6 (pattern 3+3) and greater than or equal to 6 mm Maximum Cancer Core Length, or MCCL, or a Gleason score 7 (pattern 3+4 or 4+3) and lesser than or equal to 10 mm MCCL, which is thought to have the potential to progress and would therefore warrant treatment. (A Gleason score is a grading system utilized to describe how aggressive a prostate tumor is and how likely it is to spread. Generally, there are five recognized Gleason histological scores and a higher Gleason score indicates a more aggressive tumor.) The primary objective of the study is safety and tolerability of an injection of topsalysin and the key efficacy variable is focal ablation of a clinically significant lesion on biopsy at 24 weeks. This study is enrolling approximately 40 patients at clinical sites in the UK and US. Five clinical trial sites have been initiated and additional sites are in the process of being initiated. We expect to receive biopsy data for all patients conducted 24 weeks after the initial dose in the first quarter of 2018, assuming enrollment is completed as expected.

Based upon the results of the 24 week biopsy, the study includes an option to potentially re-treat the targeted lesion area with a second dose of topsalysin, with a targeted biopsy to occur 24 weeks following the second dose. In order to be eligible for a second dose, a patient cannot have experienced a significant adverse event attributable to topsalysin or the dosing procedure from the first dose and a patient will need to have had a clinical response from the first dose but still have the presence of a clinically significant lesion area. Based on our current timeline, we expect to have final biopsy data on all patients who receive a second dose in the fourth quarter of 2018.

W e have completed a single-center, open-label Phase 2a proof of concept clinical trial of topsalysin for the treatment of localized low to intermediate risk prostate cancer. The primary objective of the trial was to assess the safety and tolerability of topsalysin when used to selectively target and focally ablate a clinically significant tumor. The potential efficacy was evidenced by histological changes, indicating tumor ablation at six months following treatment.

A total of 18 patients with localized low to intermediate risk prostate cancer were enrolled in the Phase 2a proof of concept clinical trial. On June 9, 2016, we announced the biopsy results from all 18 patients enrolled in the Phase 2a proof-of-concept study of topsalysin for the treatment of localized prostate cancer. The one-time administration of topsalysin was well tolerated with no serious adverse events and no new safety signals being reported. Topsalysin demonstrated an ability to ablate tumor cells in 50 percent of patients (9/18 patients) six months after treatment in a patient population with pre-identified, clinically significant prostate cancer. In preparation for the presentation of the Phase 2a proof of concept clinical trial data for an upcoming medical conference, we recently determined that 2 patients who were initially reported as having no response to treatment should have been reported as having a partial response to treatment. Taking into account the updated results, topsalysin demonstrated an ability to ablate tumor cells in more than 60 percent of patients (11/18 patients) six months after treatment in a patient population with pre-identified, low to intermediate risk prostate cancer.

All 18 patients enrolled completed the study. Biopsy data at six months following treatment showed that:

- Two patients experienced complete ablation of their targeted tumor with no evidence of any tumor remaining at six months;
- Nine patients experienced a partial response, defined as either a reduction in the maximum cancer core length or a reduction in Gleason pattern; and
- Seven patients had no response to treatment.

We have also completed the first of two Phase 3 clinical trials that we believe would be required to obtain marketing approval for topsalysin for the treatment of the symptoms of BPH. In October 2013 we initiated our first Phase 3 clinical trial, which we refer to as the "PLUS-1" trial, of topsalysin for the treatment of the lower urinary tract symptoms of BPH. The Phase 3 "PLUS-1" trial was an international, multicenter, randomized, double-blind, and vehicle-controlled trial to assess the efficacy and safety of a single intraprostatic administration of topsalysin (0.6 µg/g prostate) for the treatment of the lower urinary symptoms of BPH. Patients were randomized on a 1:1 ratio to either topsalysin or vehicle-only injection, and then monitored for one year. A total of 479 patients with moderate to severe BPH were enrolled and randomized by September 2014. On November 10, 2015, we announced final results from this trial. Topsalysin demonstrated a statistically significant improvement in International Prostate Symptom Score, IPSS, total score from baseline over 12 months compared to the vehicle-only control group (7.60 vs. 6.58 point overall improvement; $p = 0.043$), the primary endpoint of the trial. (IPSS is a patient recorded, composite assessment that takes into account factors such as ability to empty the bladder, frequency of urination, intermittency of urination, urgency of urination, weak strength of urine stream, straining while urinating, and having to urinate at night after going to bed.) Topsalysin continues to demonstrate a favorable safety profile, with no evidence of any treatment related sexual or cardiovascular side effects.

We are currently not planning on pursuing a second Phase 3 trial in BPH, unless we secure a development partner to fund such new clinical trial or obtain other financing. There can be no assurance that such funding or a development partner will be available on acceptable terms or at all. For that reason, we cannot currently estimate when the clinical development required to seek the regulatory approvals needed to commercialize topsalysin for the treatment of the symptoms of BPH will be completed.

Financial Operations Overview

Revenues

Our cumulative 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 topsalysin 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 topsalysin, which additional agreements will not likely occur until we complete the development of topsalysin. If our development efforts for topsalysin, or the efforts or Kissei or any future collaborator, result in clinical success and regulatory approval or collaboration agreements with other third parties, we may generate revenues from topsalysin. However, we may never generate revenues from topsalysin 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 topsalysin. 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.

At this time, due to the risks inherent in the clinical trial process and given the stage of our product development program, we are unable to estimate with any certainty the costs we will incur in the continued development of topsalysin for potential approval and commercialization in two indications. 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 continue for the foreseeable future as we advance topsalysin through clinical development. 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.

Essentially all of our research and development expenses related to topsalysin during the three months and six months ended June 30, 2017 and 2016. We recognized research and development expenses as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	201 7	201 6	2017	2016
Clinical research and development	$ 879	$ 906	$ 1,707	$ 1,733
Manufacturing	378	35	633	105
Stock-based compensation expense	130	37	255	69
	$ 1,387	$ 978	$ 2,595	$ 1,907

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation . 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, investor relations and legal services. We expect general and administrative expenses to remain fairly consistent over the next year but if we were to move our drug candidate towards commercialization in future periods we do expect that general and administrative expenses would increase.

Interest Expense

Interest expense represents interest payable to Oxford Finance, LLC, or Oxford , and amortization of our debt discount associated with Oxford related financings. On September 2, 2016, we repaid the outstanding balance of the Oxford Loan and Security Agreement in full.

Interest Income

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

Gain (Loss) on Revaluation of Warrant Liability

In connection with the offering s completed in 2016, we issued warrants to purchase our common shares. These warrants may require us to pay the warrant holder cash under certain provisions of the warrant and therefore we account for these warrants as a liability. As a result of these warrants being classified as a liability, we are required to calculate the fair value of these warrants at each reporting date. The fair value of these warrants is calculated utilizing a Black-Scholes pricing model. We calculated the initial fair value of these warrants at the date the warrants were issued. At each reporting date, we are required to remeasure the fair value of the warrant liability and any corresponding increase or decrease to the warrant liability is recorded as a gain (loss) on revaluation of warrant liability. In addition, if a warrant holder exercises warrants, we are required to revalue the fair value of the underlying warrants on the date of exercise and reclassify the change in the fair value from the warrant liability to contributed surplus.

Certain inputs utilized in our Black-Scholes fair value calculation may fluctuate in future periods based upon factors which are outside of our control. A significant change in one or more of these inputs used in the calculation of the fair value may cause a significant change to the fair value of our warrant liability which could also result in material non-cash gain or loss being reported in our 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, 2016 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 six months ended June 30, 2017.

Results Of Operations

Comparison of the three months ended June 30 , 2017 and 2016

The following table summarizes the results of our operations for the three months ended June 30, 2017 and 2016, together with the changes in those items in dollars (in thousands):

	Three Months Ended June 30 ,		Change
	201 7	201 6	201 7 vs. 201 6
Research and development expenses	1,387	978	409
General and administrative expenses	1,367	1,357	10
Interest expense	—	(137)	137
Interest income	53	3	50
Gain (loss) on revaluation of warrant liability	3,320	(1,619)	4,939
Other expense	(9)	(3)	(6)

Research and development expenses . Research and development expenses were $1.4 million for the three months ended June 30, 2017 compared to $1.0 million for the three months ended June 30, 2016. The increase in research and development costs is attributable to the following:

- a $ 0.5 million increase in clinical costs associated with our Phase 2b for the focal treatment of localized prostate cancer which was initiated in March 2017;
- a $0. 3 million increase in the costs associated with manufacturing activities for topsalysin; and
- a $0. 1 million increase in the non-cash stock-based compensation expense. The increase in the non-cash stock-based compensation expense is primarily associated with stock options granted to employees in December 2016.

These increases are partially offset by decreases of $0.2 million for costs associated with our completed Phase 2a proof of concept clinical trial for low to intermediate risk prostate cancer and $0.3 million for personnel related costs.

General and administrative expenses. General and administrative expenses were $1.4 million for the three months ended June 30, 2017 and 2016. General and administrative expense included non-cash stock-based compensation expense of $0.3 million for the three months ended June 30, 2017 as compared to $0.1 million for the three months ended June 30, 2016. The increase in the non-cash stock-based compensation expense is primarily associated with stock options granted to employees in December 2016 and directors in May 2017. This increase was offset by decreases for personnel related costs.

Interest expense. Interest expense was $0.1 million for the six months ended June 30, 2016. Interest expense was related to our promissory notes with Oxford. We repaid the outstanding principal balance of the Oxford Loan and Security Agreement in full in September 2016.

Interest income. Interest income was $53,000 was for the three months ended June 30, 2017 compared to $3,000 for the three months ended June 30, 2016. The increase is due to the increase in the average balances of our interest-bearing cash and investment accounts from period to period.

Gain (l oss) on revaluation of warrant liability. Gain on revaluation of the warrant liability was $3.3 million for the three months ended June 30, 2017 compared to a loss of $1.6 million for the three months ended June 30, 2016. This non-cash gain is associated with the change in the fair value of our warrant liability which is calculated using a Black-Scholes pricing model.

Other expense. Other expense was $9,000 for the three months ended June 30, 2017 compared to $3,000 for the three months ended June 30, 2016. This change was due to an increase in foreign exchange losses associated with foreign currency transactions.

Comparison of the six months ended June 30, 201 7 and 201 6

The following table summarizes the results of our operations for the six months ended June 30, 201 7 and 2016, together with the changes in those items in dollars (in thousands):

	Six Months Ended June 3 0 ,		Change
	201 7	201 6	201 7 vs. 201 6
Research and development expenses	2,595	1,907	688
General and administrative expenses	2,736	2,521	215
Interest expense	—	(287)	287
Interest income	103	7	96
Gain (l oss) on revaluation of warrant liability	3,234	(1,619)	4,853
Other expense	(16)	(7)	(9)

Research and development expenses . Research and development expenses were $2.6 million for the six months ended June 30, 2017 compared to $1.9 million for the six months ended June 30, 2016. The increase in research and development costs is attributable to the following:

- a $ 1.0 million increase in clinical costs associated with our Phase 2b for the focal treatment of localized prostate cancer which was initiated in March 2017;
- a $0. 5 million increase in the costs associated with manufacturing activities for topsalysin; and
- a $0. 2 million increase in the non-cash stock-based compensation expense, primarily associated with stock options granted to employees in December 2016.

These increases are partially offset by decreases of $0.4 million for costs associated with our completed Phase 2a proof of concept clinical trial for low to intermediate risk prostate cancer and $0.4 million for personnel related costs.

General and administrative expenses. General and administrative expenses were $2.7 million for the six months ended June 30, 2017 compared to $2.5 million for the six months ended June 30, 2016. The increase from the six months ended June 30, 2016 as compared to the six months ended June 30, 2017 is primarily due to an increase in professional services and non-cash stock-based compensation expense. The increase in the non-cash stock-based compensation expense is primarily associated with stock options granted to employees in December 2016 and directors in May 2017. These increases are partially offset by the decreases in personnel related costs, legal and closing costs which were expensed as they were allocated to the warrants issued in our completed financing during the six months ended June 30, 2016.

Interest expense. Interest expense was $0.3 million for the six months ended June 30, 2016. Interest expense is related to our promissory notes with Oxford. We repaid the outstanding principal balance of the Oxford Loan and Security Agreement in full in September 2016.

Interest income. Interest income was $0.1 million for the six months ended June 30, 2017 compared to $7,000 for the six months ended June 30, 2016. The increase is due to the increase in the average balances of the interest-bearing cash and investment accounts from period to period.

Gain (l oss) on revaluation of warrant liability. Gain on revaluation of the warrant liability was $3.2 million for the six months ended June 30, 2017 as compared to a loss of $1.6 million for the six months ended June 30, 2016. This non-cash gain is associated with the change in the fair value of our warrant liability which is calculated using a Black-Scholes pricing model.

Other expense. Other expense was $16,000 for the six months ended June 30, 2017 compared to $7,000 for the six months ended June 30, 2016. This change was primarily due to a decrease in foreign exchange losses associated with foreign currency transactions.

Liquidity and Capital Resources

Overview

Since our inception, our operations have been primarily financed through public and private equity sales, debt financings 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 June 30, 2017 we had cash, cash equivalents and securities available-for-sale of $24.0 million and working capital of $23.4 million. We expect that our cash, cash equivalents and securities available-for-sale will be sufficient to fund our operations to the end of 2018. At this point in time we do not plan on pursuing a second Phase 3 trial in BPH unless we obtain additional financing. We could use dilutive funding options to fund a second Phase 3 trial in BPH such as an equity financing and non-dilutive funding options such as a partnering arrangement or royalty agreement. There can be no assurance that such funding will be available on acceptable terms.

Future Operations

We have devoted substantial resources to developing topsalysin, 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 financings and payments from Kissei.

We will require significant additional capital to fund our operations and complete development of topsalysin and there is no assurance that we will obtain additional capital.

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, including our second Phase 2 clinical trial for localized prostate cancer and an additional Phase 3 clinical trial for BPH, preclinical studies and other research and development activities for topsalysin;
- 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 topsalysin.

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

Cash Flows

The following table shows a summary of our cash flows for the six months ended June 30, 2017 and 2016 (in thousands):

	Six Months Ended June 30 ,	
	201 7	201 6
Net cash provided by (used in):		
Operating activities	$ (4,869)	$ (4,735)
Investing activities	(1,110)	2,500
Financing activities	2	4,692
Effect of exchange rate changes on cash and cash equivalents	1	—
Net decrease in cash and cash equivalents	$ (5,976)	$ 2,457

Operating Activities

Net cash used in operating activities increased to $4.9 million for the six months ended June 30, 2017 from $4.7 million for the six months ended June 30, 2016. The increase in net cash used in operating activities of $0.2 million was primarily due to the use of cash for upfront fees paid to our research and development organizations assisting with our clinical trial and manufacturing activities, offset by the decrease in funds used for the payment of accounts payable.

Investing Activities

Net cash used in investing activities was $1.1 million for the six months ended June 30, 2017, compared to $2.5 million net cash provided by investing activities for the six months ended June 30, 2016. The net cash used in investing activities during the six months ended June 30, 2017 represents the usage of cash to purchase securities classified as available-for-sale. The net cash provided by investing activities during the six months ended June 30, 2016 represents 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 $2,000 for the six months ended June 30, 2017, compared to $4.7 million cash provided by financing activities for the six months ended June 30, 2016. The cash provided by financing activities for the six months ended June 30, 2017 are proceeds from the exercise of stock options. The cash provided by financing activities in the six months ended June 30, 2016 are the net proceeds from our completed financing in May 2016 and proceeds from the exercise of warrants.

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.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued new guidance related to revenue recognition (ASU No. 2014-09 Revenue from Contracts with Customers (Topic 606)). Subsequently the FASB has issued additional guidance (ASU Nos. 2015-14; 2016-08; 2016-10; 2016-12; 2016-20 Revenue from Contracts with Customers (Topic 606)). The guidance establishes principles for reporting information about the nature, amount, timing, and uncertainty of revenue and cash flows arising from an entity ’s contracts with customers. The guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Two methods of adoption are permitted: (a) full retrospective adoption, meaning the standard is applied to all periods presented or (b) modified retrospective adoption, meaning the cumulative effect of applying the new guidance is recognized as an adjustment to the opening retained earnings balance. We did not recognize any revenue from contracts with customers in the years ended December 31, 2016, 2015 and 2014. Although we are still evaluating the impact of the new standard, we anticipate that the impact will not be material to the consolidated financial statements as we do not currently generate revenues from contracts with customers.

In February 2016, the FASB issued ASU, No. 2016-02, " *Lease* s *(Topic 842)* ". This guidance requires lessees to recognize a lease liability and a right-of-use asset with the exception of short-term leases. In addition, lessees are required to classify leases as either operating or finance based on current criteria of whether or not the lease is effectively a financed purchase by the lessee. The new standard is effective for the annual reporting period beginning after December 15, 2018 and early adoption is permitted. Although we are in the process of evaluating the impact of this guidance on its consolidated financial statements and related disclosures, we expect that our operating lease will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon adoption.

In August 2016, the FASB issued ASU 2016-15, " *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments",* addressing eight specific cash flow issues in an effort to reduce diversity in practice. The amended guidance is effective for fiscal years beginning after December 31, 2017, and for interim periods within those years. Early adoption is permitted. We are in the process of evaluating the impact of this guidance on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *"Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting"* . The new standard provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The new standard will be effective for us on January 1, 2018; however, early adoption is permitted. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

Item 3. Qualitative and Quantitative Disclosures About Market Risk

Under SEC rules and regulations, as a smaller reporting company, we are not required to provide the information required by this item .

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 chief 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 June 30, 2017, 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 June 30, 2017.

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.

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, or SEC on March 2 7 , 2017 .

Risks Related to Our Business and Industry

We will require significant funding to complete the development and commercialization of topsalysin 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 or cease operations.

Our operations have consumed substantial amounts of cash since inception. Since inception, we have raised approximately $146 million from the sale of equity securities in private placements and public offerings, $21 million from the issuance of debt securities, and $11 million from the exercise of common share purchase warrants. We will need to continue to spend substantial amounts to continue clinical development of topsalysin. We are currently evaluating options to further advance the clinical development of topsalysin. We have initiated a second Phase 2 clinical trial to confirm the dose and optimize the delivery of topsalysin for the treatment of localized prostate cancer. We will require significant additional funding to advance topsalysin in clinical development outside of this second Phase 2 clinical trial. We could use dilutive funding options such as an equity financing and non-dilutive funding options such as a partnering arrangement or royalty agreement to fund future clinical development of topsalysin. Other than our second Phase 2 clinical trial for the treatment of localized prostate cancer, at this point in time we do not plan on pursuing new clinical trials, including a second Phase 3 trial in BPH, unless we obtain additional financing or secure a development partner to fund such new clinical trials. There can be no assurance that such funding or a development partner will be available on acceptable terms or at all.

We expect that our existing cash, cash equivalents and securities available-for-sale, together with interest thereon, will only be sufficient to fund our operations to the end of 2018. 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. Any clinical development efforts, including our second Phase 2 clinical trial and our ongoing operations will require significant funding.

We expect to finance future cash needs through public or private equity offerings, debt financings or strategic partnerships and alliances and licensing arrangements. In addition, as part of our offering of common shares in August 2016, we agreed not to sell any equity securities for 90 days from the closing. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may need to significantly delay, scale back or discontinue the development or commercialization of topsalysin. We also could be required to:

- seek collaborators for one or more of our current or future product candidates on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- seek a third party to acquire us or our assets.

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

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. We are at an early stage of development of our product candidate, topsalysin, for the treatment of the lower urinary tract symptoms of benign prostatic hyperplasia, or BPH and for the treatment of clinically significant localized prostate cancer. Topsalysin requires significant additional clinical testing and investment prior to seeking marketing approval for either the treatment of the symptoms of BPH or the treatment of prostate cancer. On November 10, 2015, we announced final results from our Phase 3 "PLUS-1" study of topsalysin as a treatment for lower urinary tract symptoms of BPH. However, in order to seek regulatory approval for the treatment of the symptoms of BPH, we would be required to conduct a second Phase 3 clinical trial. At this point in time we do not plan on pursuing a second Phase 3 trial in BPH unless we obtain additional financing or secure a development partner to fund such new clinical trial. There can be no assurance that such funding or a development partner will be available on acceptable terms or at all. In May 2015, we initiated a Phase 2a proof of concept clinical trial of topsalysin for the treatment of localized low to intermediate risk prostate cancer and on June 9, 2016, we announced the biopsy data of all 18 patients. We have initiated a second Phase 2 clinical trial to confirm the dose and optimize the delivery of topsalysin for the treatment of localized prostate cancer, which will be conducted across clinical sites in the UK and US . While we believe that we may be able to seek regulatory approval for topsalysin for the treatment of localized prostate cancer with one Phase 3 clinical trial, we have not discussed late-stage clinical development in this indication with the Food and Drug Administration, or FDA, or foreign regulatory authorities and these authorities may disagree with our assessment and require additional clinical trials or other studies before we can submit for regulatory approval. We will continue to refine our development plans for topsalysin for the treatment of localized prostate cancer based on the results of our second Phase 2 clinical trial and discussions with regulatory agencies and may change our assessment of required clinical trials and our development plan. A commitment of substantial resources by us and potential partners will be required to conduct additional clinical trials for topsalysin to meet applicable regulatory standards, obtain required regulatory approvals, and to successfully commercialize this product candidate for the treatment in either indication. Topsalysin is not expected to be commercially available for either indication for several years, if at all, and any projected timelines for commercialization are subject to a number of factors that are outside our control. There is no assurance that we will be able to commercialize topsalysin within the time periods we expect or that our clinical trials will support the regulatory approvals needed to commercialize topsalysin at all.

We are highly dependent on the success of our sole product candidate, topsalysin 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 topsalysin for the lower urinary tract symptoms of BPH and for the treatment of clinically significant localized prostate cancer, including conducting preclinical and clinical trials. We have no product candidates in our clinical development pipeline other than topsalysin, which we are developing for those two potential indications. 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 raise capital to fund our development programs and to develop, obtain regulatory approval for and then successfully commercialize topsalysin for either of these indications in the United States and the European Economic Area, or EEA. Before we can market and sell topsalysin in the United States or foreign jurisdictions for any indication, 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 topsalysin in either indication. If we do not receive regulatory approvals, our business, prospects, financial condition and results of operations will be adversely affected. Even if we obtain the regulatory approvals to market and sell topsalysin, we may never generate significant revenues from any commercial sales of topsalysin for several reasons, including because the market for topsalysin may be smaller than we anticipate, topsalysin may not be adopted by physicians and payors or because topsalysin may not be as efficacious or safe as other treatment options. If we fail to successfully commercialize topsalysin, 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.

The clinical trial protocol and design for our completed and any additional future Phase 3 clinical trials of topsalysin may not be sufficient to allow us to submit a BLA to the FDA in the indication of lower urinary tract symptoms of BPH or demonstrate safety or efficacy at the level required by the FDA for product approval.

Our initial Phase 3 clinical trial in the treatment of lower urinary tract symptoms of BPH and any additional Phase 3 clinical trial of topsalysin in this indication use the International Prostate Symptom Score, or IPSS, outcome measure evaluated at total change from baseline over 52 weeks as the primary endpoint. Secondary endpoints include Qmax (maximum urine flow) change from baseline (maximum urine flow) over 52 weeks. The IPSS outcome measure, which is a validated primary efficacy endpoint used to assess the treatment benefit in BPH clinical trials, is a patient recorded, composite assessment that takes into account factors such as ability to empty the bladder, frequency of urination, intermittency of urination and the urgency of urination. The IPSS outcome measure is subjective in nature and requires patients in the trial to accurately and retroactively assess numerous symptoms. The subjective nature of the IPSS outcome measure may make efficacy more difficult to demonstrate than for clinical trials for therapies that can show objective measures of efficacy.

We have not requested 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 initial Phase 3 clinical trial and any future Phase 3 clinical trials has or will generate data sufficient to establish the effectiveness of topsalysin for treatment of BPH symptoms to the FDA's satisfaction, and therefore allow us to submit or receive approval of a Biologics License Application, or BLA for topsalysin. If the FDA requires us, or we otherwise determine, to amend our protocols, change our clinical trial designs, increase enrollment targets or conduct additional clinical trials, our ability to obtain regulatory approval on the timeline we have projected would be jeopardized and we could be required to make significant additional expenditures related to clinical development.

Further, even if we achieve positive results on the endpoints for a clinical trial, the FDA may disagree with our interpretation of the data and deem the results insufficient to demonstrate efficacy at the level required by the FDA for product approval. It is possible that we may make modifications to the clinical trial protocols or designs of our future clinical trials that delay enrollment or completion of such clinical trials and could delay regulatory approval of topsalysin for the treatment of symptoms of BPH. Any failure to obtain approval for topsalysin 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.

Our clinical trials may fail to adequately demonstrate safety and efficacy of topsalysin for either indication being pursued. Failure to meet the safety or efficacy standards for the trial would prevent or delay regulatory approval and commercialization.

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

On November 10, 2015, we announced the final results from our initial Phase 3 clinical trial of topsalysin for the treatment of lower urinary tract symptoms of BPH and we are currently considering an additional Phase 3 clinical trial for topsalysin to examine whether topsalysin will effectively relieve BPH symptoms as measured at 52 weeks following treatment, which second trial will be required by the FDA before we can seek marketing approval of topsalysin in this indication. The results of the initial Phase 3 clinical trial may not be predictive of the second required Phase 3 clinical trial in the same indication. Further, even if we meet the primary and secondary endpoints in both trials, if topsalysin is slow to achieve effectiveness, this may limit its commercial potential relative to therapies that demonstrate more immediate effect on the symptoms of BPH. The FDA has not agreed upon the amount of IPSS treatment effect that must be demonstrated in the required Phase 3 clinical trials in order for marketing approval to be granted; however, historically the oral medications approved for the treatment of BPH have shown approximately a 2 point improvement in IPSS between active and control. There is no assurance that the FDA will not require that we demonstrate a 2 point improvement, which was not seen in the PLUS-1 clinical trial.

On June 9, 2016, we announced the biopsy data at six months on all 18 patients enrolled in our Phase 2a proof of concept clinical trial of topsalysin for the treatment of localized low to intermediate risk prostate cancer. The results of the Phase 2a proof of concept clinical trial may not be predictive of the results of our next Phase 2 study to confirm dosing and optimize delivery.

If any of the clinical trials of topsalysin fail to demonstrate sufficient safety and efficacy, we would experience potentially significant delays in, or be required to abandon our development program, which would have a material and adverse impact on our business, prospects, financial condition and results of operations.

We may seek a partner for the continued development and commercialization of topsalysin for the treatment of the symptoms of BPH. If we seek a partner and are unable to find a partner or such partnership is unsuccessful, we may be unable to commercialize topsalysin for this indication.

We may seek a third-party partner for financial and scientific resources for the further clinical development and commercialization of topsalysin for the treatment of the symptoms of BPH, including the required second Phase 3 clinical trial. There is no assurance that we will be able to find such a partner and, if we do, we may have to relinquish a significant portion of the future economic value of topsalysin to such partner. Also, a partner will likely significantly limit our control over the course of clinical development of topsalysin. Our ability to recognize revenue from a successful partnering arrangement of the sort we are contemplating may be impaired by several factors, including:

- a partner may shift its priorities and resources away from topsalysin due to many reasons, including a change in business strategy, a merger, acquisition, sale or downsizing of its company or business unit;
- successfully identifying a new partner and negotiating an agreement could be more difficult or the terms less advantageous because we have already established a partnership for Japan;
- a partner may have the ability to unilaterally cease development of topsalysin;
- a partner may change the success criteria for topsalysin as a treatment for the symptoms of BPH thereby delaying or ceasing clinical development of topsalysin;
- a partner could develop a product that competes, either directly or indirectly, with topsalysin;
- a partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of topsalysin;
- a partner could terminate our agreement;
- a dispute could arise between us and a partner concerning the research, development or commercialization of topsalysin which could delay or terminate development and, possibly, result in costly litigation or arbitration which may divert management attention and resources; and
- a partner may use our proprietary information or intellectual property in such a way as to invite litigation from a third party or fail to maintain or prosecute intellectual property rights such that our rights are jeopardized.

In addition, any adverse developments that occur during any clinical trials conducted by or under the supervision of a partner may affect our ability to obtain regulatory approval or commercialize topsalysin for the treatment of prostate cancer.

Further, if a partnership terminates or is otherwise unsuccessful, we may need to seek out and establish an alternative partnership. This may not be possible, or we may not be able to do so on terms which are acceptable to us, in which case, it may be necessary for us to cease the development of topsalysin for the treatment of symptoms of BPH or conduct the remaining clinical development on our own and with our own funds.

Any of these events would have a material adverse effect on our results of operations and financial condition.

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

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. Topsalysin is subject to regulation in the United States as a biologic. Biologics require the submission of a BLA, and we are not permitted to market topsalysin in the United States until we obtain approval from the FDA of a BLA. To market topsalysin 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 submission date for a standard application and eight months from the submission date for a priority review application. The FDA ’s review goals are subject to change, and it is unknown whether the review of a BLA for topsalysin will be completed within the FDA’s target timelines or will be delayed. Moreover, the duration of the FDA’s review may depend on the number and types of other BLAs that are submitted to the FDA around the same time period or are pending. Generally, public concern regarding the safety of drug products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

We 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 topsalysin. 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 any BLA for topsalysin. 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.

Topsalysin 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 topsalysin 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 topsalysin and generating revenues from its sale. The most common adverse events observed in patients who received topsalysin in our initial Phase 3 clinical trial for the treatment of lower urinary tract symptoms of BPH that were potentially attributable to topsalysin included painful urination, the presence of red blood cells in urine, frequent urination and urinary urgency, fever, and perineal pain. Each of the foregoing adverse events occurred in greater than 5% of the topsalysin population. Further, the incidence of serious AEs, or SAEs, was similar in patients treated with topsalysin and vehicle. There were two SAEs assessed by the investigator as at least possibly related to treatment for topsalysin and one such SAE for vehicle. The topsalysin-related SAEs were moderate events of "acute non-infectious prostatitis" and "fever following prostate procedure" not unexpected manifestations of the intraprostatic cellular destruction and resultant inflammation integral to the topsalysin mechanism of action. The vehicle-related SAE was a mild event of "urinary tract infection." The adverse events which occurred in our Phase 2a localized prostate cancer trial were similar in nature to the adverse events noted in our BPH program and no SAEs were reported. Although the SAEs were moderate and not unexpected, they may not be fully indicative of the adverse events that would be encountered in commercial use or in larger trials. Results from our future 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 topsalysin for its targeted indication. Further, such side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. Any of these occurrences may have a material and adverse impact on our business, prospects, financial condition and results of operations.

In addition, if topsalysin receives marketing approval for the treatment of the symptoms of BPH or prostate cancer, or both, and we or others later identify undesirable side effects caused by topsalysin, a number of significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of topsalysin;
- 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 topsalysin;
- we may be required to change the way topsalysin is administered;
- we may choose to recall, withdraw or discontinue sale of topsalysin;
- 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 topsalysin, 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 have completed the first of two required Phase 3 clinical trials of topsalysin for the treatment of the symptoms of BPH and completed a Phase 2a proof of concept clinical trial for the treatment of localized low to intermediate risk prostate cancer, and have commenced a Phase 2b trial for the treatment of clinically significant localized prostate cancer, we do not know whether or when we will be able to fund any additional clinical trials for either the treatment of clinically significant localized prostate cancer or the treatment of the symptoms of BPH, or if any future trials will be completed on time, or at all.

Further, the commencement or completion of clinical trials can be delayed for a variety of reasons, including delays in or related to:

- raising sufficient capital or securing a development partner to fund the clinical trial;
- obtaining regulatory approval, or feedback on trial design necessary, to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- identifying, recruiting and enrolling suitable patients to participate in a clinical trial;
- catastrophic loss of drug product due to shipping delays or delays in customs in connection with delivery of drug product to foreign countries for use in clinical trials;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining sufficient quantities of topsalysin and the diluent used with topsalysin for use in clinical trials and completing reformulation of topsalysin and obtaining sufficient quantities of the reformulated topsalysin for commercial fill and finish for use in any future Phase 3 clinical trials;
- having patients complete a trial or return for post-treatment follow-up;
- adding new clinical trial 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. We do not expect to commence enrollment of our second required Phase 3 clinical trial in this indication until we have raised the additional capital required to fund such second Phase 3 clinical trial.

We may face competition to enroll prostate cancer and BPH patients in our future 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 current Phase 2b clinical trial or any future clinical trials of topsalysin would result in delays in our ability to pursue regulatory approval of topsalysin.

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 topsalysin, 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 topsalysin, other therapies for the same indications may have been introduced to the market during the period we have been delayed and such therapies may have established a competitive advantage over our product candidates.

**** We rely on third parties to manufacture topsalysin and an ingredient used in the diluent used to administer topsalysin, and we intend to rely on third parties to manufacture commercial supplies of topsalysin, if and when it is approved. The development and commercialization of topsalysin 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 topsalysin on a clinical or commercial scale. Instead, we currently rely on our third-party manufacturing partner, Boehringer Ingelheim RCV GmbH & Co KG, or BI, located in Austria for the production of topsalysin and located in Germany for fill and testing services, pursuant to an agreement which we entered into in 2011. Although we have entered into an agreement for the manufacture of clinical supplies and initial commercial supplies of topsalysin, 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.

We have completed scale-up up to the commercial batch size for topsalysin drug substance, but the finalization of the commercial fill finish process for the production of drug product is still underway. In addition, we have decided to pursue the reformulation of topsalysin, including the diluent. Reformulation could result in significant delays in the commencement of future clinical trials. In addition, we will need to have additional drug substance manufactured for us and there is no assurance that we can secure a favorable manufacturing timetable. Moreover, we have not entered into a commercial supply agreement with BI and BI has not demonstrated that it will be capable of manufacturing the filled and finished topsalysin on a large commercial scale. If BI is unable or unwilling to manufacture the filled and finished topsalysin on a large commercial scale, we may be required to identify a new manufacturer and engage in technology transfer which could cause significant delays in finalizing the drug manufacturing process and could cause delays to future planned clinical trials.

BI currently procures an ingredient used in the current formulation of topsalysin from a multinational industrial biotech company which is a single source supplier, on a purchase order basis. 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.

The facilities used by our third-party manufacturer to manufacture topsalysin 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 topsalysin in accordance with cGMPs, which include, among other things, quality control, quality assurance and the maintenance of records and documentation.

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

Topsalysin 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.

We have relied upon and expect to rely upon multiple CROs to conduct and oversee our completed and any future clinical trials for topsalysin. 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 clinical trials of topsalysin and expect to rely upon CROs for any future clinical trials. 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 topsalysin. We will rely heavily on these third parties for the execution of our future 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.

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

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

Kissei Pharmaceutical Co., Ltd., or Kissei, retains the rights to develop and commercialize topsalysin 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 any other clinical trials Kissei decides to conduct with respect to topsalysin, the FDA and other regulatory authorities may delay, limit or deny approval of topsalysin 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 topsalysin 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 topsalysin.

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 topsalysin.

We expect that topsalysin will compete with the current treatment options for the treatment of clinically significant localized prostate cancer, which include surgical options such as laparoscopic and radical prostatectomy or radiation. In addition, there are other focal targeted therapies which are gaining traction that are currently in clinical development or have been recently approved which include: brachytherapy, cryotherapy, high focused ultrasound, cyber knife, radio frequency ablation and laser ablation. In addition, in 2016, Nymox Pharmaceuticals announced the clinical trial results from 18 months with the intraprostatic administration of their investigational therapy NX-1207 (fexapotide triflutate) in patients with low grade localized (T1c) prostate cancer, and, in January 2016, Steba Biotechnology submitted a Marketing Authorization Application to the European Medicine Agency for the focal treatment of patients with low risk localized prostate cancer, with their vascular –targeted photodynamic therapy TOOKAD.

We expect that topsalysin will compete with the current treatment options for the symptoms of BPH, which include oral drug therapy and surgery. Oral drug therapies include (a) alpha-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-alpha 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-alpha reductase inhibitors such as tamsulosin and dutasteride (marketed by GSK as Jalyn ®) and (d) tadalafil (marketed as Cialis ® by Eli Lilly), a PDE5 inhibitor which obtained FDA approval for the treatment of the symptoms of BPH in October 2011. Several minimally invasive surgical therapies, or MIST, are available, including transurethral microwave thermotherapy, or TUMT, transurethral needle ablation, or TUNA, photo-selective vaporization of prostate, holmium laser enucleation of the prostate, transurethral electrovaporization of the prostate, interstitial laser coagulation, and the UroLift ® system (marketed by NeoTract, Inc.), which is an implant delivered into the body via a small needle and designed to hold prostate tissue out of the way of the blocked urethra. Currently, the most commonly used MIST procedures are laser ablations of the prostate, TUMT, and TUNA. Surgery for BPH treatment is usually considered in patients who fail drug therapy as a result of side effects or inadequate relief of symptoms, have refractory urinary retention, or have recurrent urinary tract infections. Alternatively, surgery may be the initial treatment in patients with severe urinary symptoms. Surgical procedures for BPH include transurethral resection of the prostate, as well as other procedures such as transurethral incision of the prostate and transurethral vaporization of the prostate. In May 2017, Nymox Pharmaceuticals announced that it had filed for marketing authorization for Fexapotide Triflutate for the treatment of the symptoms of BPH in five European countries, the Netherlands, the United Kingdom, Germany, France and Spain. In addition, there are other treatments that are currently in clinical development for the treatment of the symptoms of BPH. Light Sciences Oncology Inc.'s Aptocine ™ is currently in Phase 2 clinical trials; and in late 2015, Procept BioRobotics announced the first patients had been treated in a Phase 3 clinical trial to evaluate the AquaBeam System, a waterjet ablation therapy for endoscopic resection of prostate tissue.

The availability and price of our competitors ' products and procedures could limit the demand, and the price we are able to charge, for topsalysin. We will not successfully execute on our business objectives if the market acceptance of topsalysin is inhibited by price competition, if physicians are reluctant to switch from existing products or procedures to topsalysin or if physicians switch to other new products or surgeries or choose to reserve topsalysin 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 topsalysin 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 topsalysin from the FDA in either indication, we may never obtain approval for topsalysin outside of the United States, which would limit our market opportunities and adversely affect our business.

Sales of topsalysin 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 topsalysin will be harmed and our business will be adversely affected.

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

Any regulatory approvals that we obtain for our product candidate may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including 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 federal Drug Supply Chain Security Act, imposes 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, manufacturers 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.

If we fail to comply with health care laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations, including those pertaining to fraud and abuse and patients ’ rights, are and will be applicable to our business. We could be subject to healthcare regulation by both the federal government and the states in which we conduct our business. The health care laws and regulations that may affect our ability to operate include, without limitation: anti-kickback statutes, false claims statutes patient data privacy and security laws, and physician sunshine laws and regulations, many of which may become more applicable if our product candidates are approved and we begin commercialization. If our operations are found to be in violation of any of these laws or regulations, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, and exclusion from participation in federal healthcare programs, as well as contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Any such penalties could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws and regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Moreover, achieving and sustaining compliance with these laws and regulations may prove costly.

**** 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 June 30, 2017, we had six full-time employees. In May 2016, we had a reduction in force of five employees to preserve our cash resources while we pursue strategic alternatives. If we obtain additional capital we may have to rehire these employees or identify and hire replacements. In addition, we have engaged part-time individual consultants to assist us with 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;
- 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.

Our limited operating history makes evaluating our business and future prospects difficult.

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.

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

Topsalysin, if approved in either indication for which we are currently pursuing development or any other indication, may not attain market acceptance among physicians, patients, healthcare payors or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from topsalysin will depend on a number of factors, including:

- timing of market introduction of our products as well as competitive drugs;

- efficacy and safety of topsalysin;
- the clinical indication(s) for which topsalysin is approved;
- continued projected growth of the urological disease markets, including incidence of BPH and prostate cancer;
- acceptance by patients, primary care specialists and key specialists, including urologists for BPH and urologists and oncologists for prostate cancer;
- potential or perceived advantages or disadvantages of topsalysin over alternative treatments, for BPH including cost of treatment and relative convenience and ease of administration and length of sustained benefits from treatment;
- potential or perceived advantages or disadvantages of topsalysin over alternative treatments, for BPH 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 topsalysin, 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 payors; and
- product labeling or product insert requirements of the FDA or other regulatory authorities.

If topsalysin is approved in either or both indications but fails to attain market acceptance by physicians, patients, health care payors, 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 topsalysin, which could make it difficult for us to sell topsalysin profitably.***

Market acceptance and sales of topsalysin 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 payors 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 payor reimbursement for the cost of topsalysin and/or payment to the physician for administering topsalysin. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. 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 payor separately, with no assurance that coverage and adequate reimbursement will be obtained. One third-party payor ’s decision to cover a particular medical product or service does not assure that other payors 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 payor separately, with no assurance that adequate coverage and reimbursement will be obtained. Further, a third-party payor’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 payors’ formularies, or lists of treatments for which third-party payors provide coverage and reimbursement.

Third-party payors establish coverage and reimbursement policies for new products, including product candidates like topsalysin. In particular, in the United States, private health insurers and other third-party payors 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 payors 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 payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the 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 the 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 with income at or below 133% of the Federal Poverty Level, 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 federal civil 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.

Since its enactment there have been judicial and Congressional challenges to other aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future. As a result there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the PPACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The U.S. House of Representatives passed legislation known as the American Health Care Act of 2017 in May 2017. More recently, the Senate Republicans have released and then updated a draft bill known as the Better Care Reconciliation Act of 2017. Each of these Congressional proposals would repeal and replace certain aspects of the PPACA if ultimately enacted. The Senate Republicans have also contemplated legislation to repeal the PPACA without companion legislation to replace it. The prospects for enactment of these legislative initiatives remain uncertain. Further, Congress also could consider other legislation to replace elements of the PPACA. We continue to evaluate the potential effect of the possible repeal and replacement of the PPACA may have on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2015, will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers. Further, recently there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products. We expect that additional federal and state healthcare reform measures will be adopted in the future, any of which could result in reduced demand for our products or other adverse effects on our business.

In the EEA, the success of topsalysin, 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 topsalysin, 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 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 topsalysin and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidate could be delayed.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, systems failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business interruptions could seriously harm our business and financial condition and increase our costs and expenses. A majority of our management operates in our principal executive offices located in San Diego, California. If our San Diego offices were affected by a natural or man-made disaster, particularly those that are characteristic of the region, such as wildfires and earthquakes, or other business interruption, our ability to manage our domestic and foreign operations could be impaired, which could materially and adversely affect our results of operations and financial condition. We currently rely, and intend to rely in the future, on our third-party manufacturer, BI, which is located in Austria and Germany, to produce our supply of topsalysin. Our ability to obtain supplies topsalysin 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 topsalysin and other hazardous compounds. Specifically, the cleavage of the PSA-sensitive activation sequence of topsalysin 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 topsalysin 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 topsalysin. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state or foreign consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidate. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product or product candidates that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management ’s time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- 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 development, and may be difficult to retain or replace. We conduct our operations at our facilities in San Diego, California and this region is headquarters to many other biopharmaceutical companies and many academic and research institutions and therefore we face increased competition for personnel in this location. Competition for skilled personnel in our market is very intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms.

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

Despite our efforts to retain valuable employees, members of our management and scientific and development teams may terminate their employment with us on short notice. Although we have written employment arrangements with all of our employees, these employment arrangements provide for at-will employment, which means that our employees can leave our employment at any time, with or without notice. In addition, we recently completed a reduction in workforce in May 2016 through which five of our ten employees were terminated. 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 and health regulatory 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 payor.

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

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

We are developing topsalysin for large patient populations served by urologists and oncologists 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 topsalysin and we must build this organization or make arrangements with third parties to perform these functions in order to commercialize topsalysin and any future products. We intend to establish (either internally or through a contract sales force) a sales force to sell topsalysin, if approved, in the United States, although any partnership that we establish for the development of topsalysin for the treatment of the symptoms of BPH will likely provide U.S. commercialization rights or co-commercialization rights to the partner for this indication. We plan to partner with third parties to commercialize topsalysin 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.

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 $11.2 million, $14.2 million, and $30.7 million during the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of $140.9 million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity and working capital. Our losses have resulted principally from costs incurred in our research activities for topsalysin. We anticipate that our operating losses will substantially increase over the next several years as we continue development of topsalysin, including the conduct of any future clinical trials for the treatment of the symptoms of BPH and our completed proof of concept clinical trial and future clinical trials for the treatment of clinically significant localized prostate cancer and the conduct of any future clinical trials for the treatment of symptoms of BPH. In addition, if we obtain regulatory approval of topsalysin, 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 topsalysin. 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 topsalysin 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 the clinical development topsalysin in one or both indications;
- obtaining U.S. and/or foreign regulatory approvals for topsalysin in one or both indications;
- manufacturing commercial quantities of topsalysin at acceptable costs levels if regulatory approvals are received;
- achieving broad market acceptance of topsalysin 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 topsalysin.

We may never be able to successfully develop or commercialize topsalysin in either indication. Even if we do obtain regulatory approval to commercialize topsalysin, 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.

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

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

At June 30, 2017, we had $24.0 million of cash, cash equivalents 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 June 30, 2017, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of cash equivalents owned by us.

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

We currently incur expenses denominated in foreign currencies, specifically in connection with our manufacturing and supply agreement with Boehringer Ingelheim RCV GmbH & Co KG for the manufacture of topsalysin, for which payments are denominated in euro. In addition, we are utilizing several clinical vendors which are located in various countries outside of the United States. These clinical vendors invoice us in the local currency of the vendor. 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 six months ended June 30, 2017 and 2016, 15.0% and 9.6% 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 topsalysin 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 topsalysin 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 topsalysin 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 topsalysin. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

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

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

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 topsalysin. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. We are aware of at least one third-party patent that may be relevant to our product candidates. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

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

We are a party to a number of technology license agreements that are essential to our business and expect to enter into additional license agreements in the future. For example, we have exclusive licenses to topsalysin from UVIC Industry Partnerships Inc. and The Johns Hopkins University. The agreements governing these exclusive licenses include provisions that permit the licensors to terminate the license agreements in a number of situations, including if we grant a security interest on the licensed technology. These licensors might claim that filings made by Oxford with the U.S. PTO or foreign jurisdictions in 2011 imposed a security interest on the applicable technology. However, no claims from these licensors have been made to date regarding violations of these license agreements as a result of these filings and these filings were released when we repaid the Oxford debt in full in 2016. Furthermore, if any such claims are made in the future, we believe that such claims would not have merit and we would vigorously defend and reject such claims. If we fail to comply with our obligations under our license agreements, or we are insolvent or subject to a bankruptcy proceeding, the applicable licensor may have the right to terminate such license agreement, in which event we would not be able to market products covered by such license agreement, including topsalysin. 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. The loss of our rights to technology that we have licensed under certain agreements would have a material adverse effect on our business.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to 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 years ending December 31, 2012, 2013, 2014 and 2015 and that we will likely be a PFIC for the taxable year ending December 31, 2016. In 2017 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 2016 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, 2016 or any subsequent year.

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 Capital Market. 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 Capital Market. These expenses relate to, among other things, the obligation to present financial information according to U.S. GAAP in the United States. We are also required to comply with certain disclosure and filing requirements under applicable securities laws in Canada as a reporting issuer in certain provinces.

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

Prior to our IPO in 2013, there was no public market for our common shares in the United States. The trading price of our common shares has been volatile and is likely to continue 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 outcome of our pursuit of strategic alternatives, including whether we raise any additional capital to fund our ongoing operations;
- the results of our completed and future clinical trials of topsalysin or changes in the development status of topsalysin;
- any adverse development or perceived adverse development with respect to our submission of a BLA to the FDA for topsalysin;
- unanticipated serious safety concerns related to the use of topsalysin;
- adverse regulatory decisions, including failure to receive regulatory approval for topsalysin;
- 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;
- trading volume of our common shares on The NASDAQ Capital Market 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.

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

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

Pursuant to our equity incentive plan, our management is authorized to grant options to our employees, directors and consultants. The number of shares available for future grant under our plan is equal to 10% of all shares of our issued and outstanding common shares at any time. 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. 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 until December 31, 2018, 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 $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

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

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

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

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 shareholders; 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.

Item 6. Exhibits

The following exhibits are filed as part of, or incorporated by reference into, this report:

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	Notice of Articles of the Company	A ttached hereto
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	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.
4.3	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.
4.4	Omnibus Amendment to Warrants to Purchase Common Shares dated February 14, 2014 by and between the Company and Oxford Finance LLC	Incorporated by reference to the Current Report on Form 8-K filed on February 18, 2014.
4.5	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.
4.6	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.
4.7	Registration Rights Agreement by and between the Company and Aspire Capital Fund, LLC dated May 16, 2014.	Incorporated by reference to the Current Report on Form 8-K filed on May 19, 2014.
4.8	Form of Common Share Purchase Warrant Issued in connection with the Company 's May 2016 Financing	Incorporated by reference to the Current Report on Form 8-K filed on May 11, 2016.
4.9	Form of Common Share Purchase Warrant Issued in connection with the Company 's August 2016 Financing	Incorporated by reference to the Current Report on Form 8-K filed on August 23, 2016.
10.1	Non-employee Director Compensation Program	Incorporated by reference to the Current Report on Form 8-K filed on March 17, 2017.
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 Annual Report on Form 10-K 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.

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 10th day of August 2017.

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

Date and Time: July 26, 2017 09:03 AM Pacific Time

BC Registry Services

Mailing Address:
PO Box 9431 Stn Prov Govt
Victoria BC V8W 9V3
www.corporateonline.gov.bc.ca

Location:
2nd Floor - 940 Blanshard Street
Victoria BC
1 877 526-1526

Notice of Articles

BUSINESS CORPORATIONS ACT

This Notice of Articles was issued by the Registrar on: October 17, 2016 04:28 PM Pacific Time

Incorporation Number: **BC0712851**

Recognition Date and Time: *January 1, 2005 12:01 AM Pacific Time as a result of an Amalgamation*

NOTICE OF ARTICLES

Name of Company:

SOPHIRIS BIO INC.

REGISTERED OFFICE INFORMATION

Mailing Address:
2900 - 550 BURRARD STREET
VANCOUVER BC V6C 0A3
CANADA

Delivery Address:
2900 - 550 BURRARD STREET
VANCOUVER BC V6C 0A3
CANADA

RECORDS OFFICE INFORMATION

Mailing Address:
2900 - 550 BURRARD STREET
VANCOUVER BC V6C 0A3
CANADA

Delivery Address:
2900 - 550 BURRARD STREET
VANCOUVER BC V6C 0A3
CANADA

DIRECTOR INFORMATION

Last Name, First Name, Middle Name:
Woods, Randy

Mailing Address:
1258 PROSPECT STREET
LA JOLLA CA 92037
UNITED STATES

Delivery Address:
1258 PROSPECT STREET
LA JOLLA CA 92037
UNITED STATES

Last Name, First Name, Middle Name:
Ekman, Lars

Mailing Address:
6009 AVENIDA CRESTA
LA JOLLA CA 92037
UNITED STATES

Delivery Address:
6009 AVENIDA CRESTA
LA JOLLA CA 92037
UNITED STATES

Last Name, First Name, Middle Name:
Hulme, Allison

Mailing Address:
1258 PROSPECT STREET
LA JOLLA CA 92037
UNITED STATES

Delivery Address:
1258 PROSPECT STREET
LA JOLLA CA 92037
UNITED STATES

Last Name, First Name, Middle Name:
HEPPELL, JAMES L.

Mailing Address:
SUITE 410 - 221 WEST ESPLANADE
NORTH VANCOUVER BC V7M 3J3
CANADA

Delivery Address:
SUITE 410 - 221 WEST ESPLANADE
NORTH VANCOUVER BC V7M 3J3
CANADA

Last Name, First Name, Middle Name:
Proehl, Gerald

Mailing Address:
7908 ENTRADA DE LUZ EAST
SAN DIEGO CA 92127
UNITED STATES

Delivery Address:
7908 ENTRADA DE LUZ EAST
SAN DIEGO CA 92127
UNITED STATES

Last Name, First Name, Middle Name:
Geltosky, Jack

Mailing Address:
1615 SORRELL ROAD
MALDERN PA 19355
UNITED STATES

Delivery Address:
1615 SORRELL ROAD
MALDERN PA 19355
UNITED STATES

RESOLUTION DATES:

Date(s) of Resolution(s) or Court Order(s) attaching or altering Special Rights and Restrictions attached to a class or a series of shares:

June 1, 2005

AUTHORIZED SHARE STRUCTURE

1.	No Maximum	Common Shares	Without Par Value With Special Rights or Restrictions attached
2.	No Maximum	Preferred Shares	Without Par Value With Special Rights or Restrictions attached

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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.) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c.) 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

d.) 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: August 10, 2017

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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.) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c.) 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

d.) 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: August 10, 2017

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 June 30, 2017 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: August 10, 2017

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 June 30, 2017, 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: August 10, 2017

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.