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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2019

☐ **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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, no par value	**SPHS**	**The Nasdaq Capital Market**

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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

Indicate by check mark whether the 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	☐	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended 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 November 1, 2019, the registrant had 34,472,140 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)

	September 30, 2019	December 31, 2018
Assets:		
Current assets:		
Cash and cash equivalents	$ 4,251	$ 10,998
Securities available-for-sale	2,050	1,541
Prepaid expenses and other current assets	710	656
Total current assets	7,011	13,195
Property and equipment, net	3	4
Operating lease right-of-use asset	85	—
Total assets	$ 7,099	$ 13,199
Liabilities and shareholders' (deficit) equity:		
Current liabilities:		
Accounts payable	$ 431	$ 1,862
Accrued expenses	745	1,192
Current portion of promissory note	2,665	1,920
Current portion of operating lease liability	85	—
Total current liabilities	3,926	4,974
Long-term promissory note	3,086	5,091
Warrant liability	2,848	1,399
Total liabilities	9,860	11,464
Commitments and contingencies		
Shareholders' (deficit) equity:		
Common shares, unlimited authorized shares, no par value; 33,572,140 and 30,205,915 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	131,489	131,247
Contributed surplus	27,459	26,714
Accumulated other comprehensive gain	100	100
Accumulated deficit	(161,809)	(156,326)
Total shareholders' (deficit) equity	(2,761)	1,735
Total liabilities and shareholders' (deficit) equity	$ 7,099	$ 13,199

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 738	$ 1,798	$ 3,382	$ 8,718
General and administrative	1,388	1,155	3,858	3,494
Total operating expenses	2,126	2,953	7,240	12,212
Other income (expense):				
Interest expense	(145)	(173)	(470)	(514)
Interest income	29	80	133	258
Gain on revaluation of warrant liability	1,281	153	2,105	143
Other income (expense), net	2	21	(11)	27
Total other income (expense)	1,167	81	1,757	(86)
Net loss	$ (959)	$ (2,872)	$ (5,483)	$ (12,298)
Basic and diluted loss per share	$ (0.03)	$ (0.10)	$ (0.18)	$ (0.41)
Weighted average number of outstanding shares – basic and diluted	32,072	30,111	30,841	30,111
Other comprehensive loss:				
Unrealized income on securities available-for-sale	1	2	—	2
Total other comprehensive loss	$ (958)	$ (2,870)	$ (5,483)	$ (12,296)

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

Sophiris Bio Inc.
Condensed Consolidated Statements of Shareholders' (Deficit) Equity
(In thousands, except share amounts)

	Common Shares		Contributed Surplus	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' (Deficit) Equity
	Shares	Amount				
Balance at July 1, 2019	30,217,140	$ 131,247	$ 27,128	$ (160,850)	$ 99	$ (2,376)
Issuance of common shares and pre-funded warrants, net of issuance costs of $43,000	3,355,000	3,796	141	—	—	3,937
Initial valuation of warrant liability upon issuance of common share purchase warrants	—	(3,554)	—	—	—	(3,554)
Stock-based compensation expense	—	—	190	—	—	190
Net loss	—	—	—	(959)	—	(959)
Other comprehensive income	—	—	—	—	1	1
Balance at September 30, 2019	33,572,140	$ 131,489	$ 27,459	$ (161,809)	$ 100	$ (2,761)
Balance at July 1, 2018	30,111,153	$ 131,247	$ 26,274	$ (158,974)	$ 97	$ (1,356)
Stock-based compensation expense	—	—	257	—	—	257
Net loss	—	—	—	(2,872)	—	(2,872)
Other comprehensive income	—	—	—	—	2	2
Balance at September 30, 2018	30,111,153	$ 131,247	$ 26,531	$ (161,846)	$ 99	$ (3,969)
Balance at January 1, 2019	30,205,915	$ 131,247	$ 26,714	$ (156,326)	$ 100	$ 1,735
Issuance of common shares and pre-funded warrants, net of issuance costs of $43,000	3,366,225	3,796	141	—	—	3,937
Initial valuation of warrant liability upon issuance of common share purchase warrants	—	(3,554)	—	—		(3,554)
Stock-based compensation expense	—	—	604	—	—	604
Net loss	—	—	—	(5,483)	—	(5,483)
Balance at September 30, 2019	33,572,140	$ 131,489	$ 27,459	$ (161,809)	$ 100	$ (2,761)
Balance at January 1, 2018	30,111,153	$ 131,247	$ 25,854	$ (149,548)	$ 97	$ 7,650
Stock-based compensation expense	—	—	677	—	—	677
Net loss	—	—	—	(12,298)	—	(12,298)
Other comprehensive loss	—	—	—	—	2	2
Balance at September 30, 2018	30,111,153	$ 131,247	$ 26,531	$ (161,846)	$ 99	$ (3,969)

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)

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows used in operating activities		
Net loss	$ (5,483)	$ (12,298)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	604	677
Accretion of debt discount	101	113
Amortization of promissory note issuance costs	39	43
Depreciation and amortization	93	2
Amortization of premium/discount on securities available-for-sale	(27)	(44)
Financing issuance cost allocated to warrant liability	359	—
Change in fair value warrant liability	(2,105)	(143)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(53)	143
Accounts payable	(1,459)	(433)
Accrued expenses	(404)	599
Operating lease liability	(92)	—
Net cash used in operating activities	(8,427)	(11,341)
Cash flows (used in) provided by investing activities		
Purchases of property and equipment	—	(4)
Maturities of securities available-for-sale	2,600	9,387
Purchases of securities available-for-sale	(3,082)	(2,081)
Net cash (used in) provided by investing activities	(482)	7,302
Cash flows provided by financing activities		
Proceeds from the issuance of common shares, pre-funded warrants and common share purchase warrants, net of paid issuance costs	3,664	—
Payment of offering costs related to the establishment of the Controlled Equity Sales Agreement	(102)	—
Principal payments on note payable	(1,400)	—
Net cash provided by financing activities	2,162	—
Net decrease in cash and cash equivalents	(6,747)	(4,039)
Cash and cash equivalents at beginning of period	10,998	16,087
Cash and cash equivalents at end of period	$ 4,251	$ 12,048
Supplemental disclosures of non-cash investing and financing activities:		
Valuation of warrant liability upon issuance of purchase warrants	$ 3,554	$ —
Unpaid issuance costs included in accounts payable	$ 86	$ —

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 focused on innovative products for the treatment of urological diseases. 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.

Liquidity

The condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The Company has incurred net losses from operations since inception, including $5.5 million in the nine months ended September 30, 2019 and has an accumulated deficit of $161.8 million as of September 30, 2019. On August 29, 2019, the Company completed a registered direct financing with a private institutional investor whereby it received $3.6 million, net of underwriters' discounts and offering costs. At September 30, 2019, the Company had cash, cash equivalents and securities available-for-sale of $6.3 million. As of September 30, 2019, the future principal and final fee payments under the Loan and Security Agreement with Silicon Valley Bank, or SVB, total $6.0 million. The maturity date of the loan is September 1, 2021. The Company is currently paying monthly installments of principal and interest under the Loan and Security Agreement. However, if the Company fails to make principal and interest payments when due or another event of default occurs under the loan, SVB may accelerate the loan and foreclose on the Company's pledged assets if the Company is unable to repay the loan in full. Events of default include the occurrence of a material adverse change as defined in the Loan and Security Agreement. As of the date of filing of this Form 10-Q, the Company is not in default under any of the provisions of the Loan and Security Agreement. The Company expects that its cash, cash equivalents and securities available-for-sale will be sufficient to fund its operations and debt service through March 2020 (assuming no acceleration of the loan) and, as a result, there is substantial doubt about its ability to continue as a going concern for one year from the date of the issuance of its condensed consolidated financial statements for the nine months ended September 30, 2019.

The Company announced that it has received formal scientific advice from the European Medicines Agency, or EMA, and reached an agreement with the U.S. Food and Drug Administration, or FDA, regarding a design for a single Phase 3 clinical trial to evaluate the potential of topsalysin as a targeted focal therapy to treat patients with intermediate risk localized prostate cancer. Based upon feedback from the EMA and the FDA, the Company believes that data from a single Phase 3 trial, if successful, should be sufficient to support market approval in both the U.S. and Europe. The scope of any additional trial in localized prostate cancer, including whether it will be a Phase 3 trial or an additional Phase 2 trial, will be dependent upon securing funding to finance such clinical trial. At this point in time, the Company does not plan on pursuing new clinical trials, including an additional trial in localized prostate cancer or a second Phase 3 trial in benign prostatic hyperplasia, or BPH, unless the Company secures a development partner to fund such new clinical trials or it obtains the necessary financing. The Company is currently evaluating options to further advance the clinical development of topsalysin. The Company will require significant additional funding to advance topsalysin in clinical development. The Company could use dilutive funding options such as an equity financing and/or non-dilutive funding options such as a partnering arrangement or other strategic arrangements to fund future clinical development of topsalysin. Any significant future public financing will most likely require the use of a Form S-1 registration statement. The process of getting a Form S-1 registration statement filed and declared effective can take an extended period of time which could delay the timing of any future significant financing. There can be no assurance that such funding will be secured in a timely manner or on favorable terms, if at all or that a development partner will be available on acceptable terms or if at all.

If the Company is unable to raise sufficient capital to fund its operations, the Company could be required to significantly reduce expenses, sell assets (potentially at a loss), cease operations altogether, file for bankruptcy or seek other protection from creditors, or liquidate all of its assets. The Company is also exploring partnership arrangements and other strategic alternatives which could include a merger or acquisition.

On March 7, 2019, the Company received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market LLC, or Nasdaq, notifying the Company that for the last 30 consecutive business days prior to the date of the letter, the market value of the Company's listed securities was less than $35 million and therefore the Company did not meet the requirement for continued listing on The Nasdaq Capital Market as required by Nasdaq Listing Rule 5550(b)(2), or the Market Value Rule, or the alternative requirements under Nasdaq Listing Rules 5550(b)(1) and 5550(b)(3). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company had 180 calendar days, or until September 3, 2019, to regain compliance with the Market Value Rule. As of the date of this filing the Company has not regained compliance with the Market Value Rule.

On June 4, 2019, the Company received a letter from the Listing Qualifications Staff of Nasdaq notifying the Company that the closing bid price of the Company's common shares had been below $1.00 per share for 30 consecutive business days and that the Company was therefore not in compliance with the minimum bid price requirement for continued listing on The Nasdaq Capital Market, as required by Nasdaq Listing Rule 5550(a)(2). Nasdaq stated in its June 4th letter that, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has a grace period of 180 calendar days, or until December 2, 2019, to regain compliance with the minimum closing bid price requirement for continued listing. The Company will regain compliance if the closing bid price of the Company's common shares is at or above $1.00 for at least 10 consecutive business days anytime during the 180-day grace period.

On September 6, 2019, the Company received a letter from the Nasdaq notifying the Company that it had not regained compliance with Market Value Rule by September 3, 2019 and as a result the Company's securities will be delisted from the Nasdaq unless the Company requests an appeal of this determination. The Company formally requested an appeal of this determination on September 12, 2019. On October 17, 2019, the Company met with the Nasdaq Hearings Panel regarding the Company's potential delisting from The Nasdaq Stock Market as a result of its failure to maintain a market value of the Company's listed securities of at least $35 million or in the alternative to have more than $2.5 million in stockholders' equity. On October 21, 2019, the Company received the Nasdaq Hearings Panel decision which granted the Company until January 24, 2020 to regain compliance with the listing standards of the Nasdaq Capital Market, by either having the market value of the Company's listed securities be at least $35 million during the preceding ten consecutive trading days before January 24, 2020 or having more than $2.5 million in stockholders' equity by January 24, 2020. The Company will also be required to have a closing bid price of at least $1.00 per share during the preceding ten consecutive trading days before January 24, 2020. If the Company is unable to regain compliance with the listing standards of the Nasdaq Capital Market by January 24, 2020, the Company's securities may be delisted from The Nasdaq Stock Market. As of the date of this filing the Company has not regained compliance with any of these listing rules.

2. Summary of significant accounting policies

Basis of consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Sophiris Bio Corp. and Sophiris Bio Holding Corp, both of which are incorporated in the State of Delaware. All intercompany balances and transactions have been eliminated for purposes of consolidation.

Basis of presentation

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 13, 2019. 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.

During the nine months ended September 30, 2019, there have been no changes to our significant accounting policies as described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, except as described below.

Leases

The Company currently leases its corporate headquarters. When the Company enters into a lease, it determines whether the agreement is a lease or contains a lease and at commencement it evaluates each lease agreement to determine whether the lease is an operating or financing lease. The Company will evaluate the lease to determine if the lease contains renewal options, tenant improvement allowances, rent holidays and rent escalation clauses. The Company adopted the Financial Accounting Standards Board Accounting Standards Update, or ASU, "Leases," or ASU 2016-02, using the modified retrospective approach with an effective date as of January 1, 2019 for leases that existed on that date. Prior period results continue to be presented under ASC 840 based on the accounting standard originally in effect for such periods.

Pursuant to ASU 2016-02, the Company's office facility lease continued to be classified as operating leases. With the adoption of ASU 2016-02, the Company recorded an operating lease right-of-use asset and an operating lease liability on its balance sheet. Right-of-use lease assets represents its right to use the underlying asset for the lease term and the lease obligation represents its commitment to make the lease payments arising from the lease. Right-of-use lease assets and obligations are recognized at the commencement date based on the present value of remaining lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company used an estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The right-of-use lease asset includes any lease payments made prior to commencement and excludes any lease incentives. The lease term may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms. The Company combines lease and non-lease components. Leases with an initial term of 12 months or less are not recorded on the balance sheet.

Prior to the Company's adoption of ASU 2016-02, when the lease agreement contained renewal options and rent escalation clauses, the Company recorded a deferred rent asset or liability equal to the difference between the rent expense and the future minimum lease payments due. The lease expense related to operating leases was recognized on a straight-line basis in the statements of operations over the term of each lease.

3. Net loss per common share

Basic net loss per share is calculated by dividing the net loss attributable to common shareholders by the weighted-average number of common shares outstanding during the period, without consideration for common shares equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common shareholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method.

The following diluted securities have been excluded from the computation of diluted weighted-average shares outstanding as of September 30, 2019 and 2018 as the Company recorded a net loss in both periods and therefore, they would be anti-dilutive (in thousands):

	September 30,	
	2019	2018
Options to purchase common shares	2,963	2,940
Common share purchase warrants	11,131	5,798

Reconciliation of shares utilized in the weighted average outstanding number of shares for basic and diluted earnings per share for the three and nine months ended September 30, 2019 and 2018:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Weighted average number of common shares outstanding during the period	31,384	30,111	30,609	30,111
Weighted average number of pre-funded warrants outstanding during the period	688	—	232	—
	32,072	30,111	30,841	30,111

Even through the impact of the inclusion of the pre-funded warrants in the earnings per shares calculation is anti-dilutive, the Company has included the pre-funded warrants issued in its August 2019 offering in the calculation of weighted average outstanding number of shares for both basic and diluted EPS for the three and nine months ended September 30, 2019 as these warrants were issued with an exercise price of $0.01 which the Company believes is nonsubstantive in relation to the fair value of the common shares to be issued upon exercise of the warrants. On October 25, 2019, 900,000 of these outstanding pre-funded warrants were exercised.

4. Securities Available-for-Sale

Securities available-for-sale consisted of the following as of September 30, 2019 (in thousands):

	September 30, 2019			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Commercial paper	$ 1,547	$ —	$ —	$ 1,547
U.S. government sponsored enterprise securities	503	—	—	503
	$ 2,050	$ —	$ —	$ 2,050

As of September 30, 2019, all of the Company's securities available-for-sale have a maturity date of less than one year.

Securities available-for-sale consisted of the following as of December 31, 2018 (in thousands):

	December 31, 2018			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Commercial paper	$ 892	$ —	$ —	$ 892
U.S. government sponsored enterprise securities	649	—	—	649
	$ 1,541	$ —	$ —	$ 1,541

As of December 31, 2018, all of the Company's securities available-for-sale have a maturity date of less than one year.

5. Fair value measurement and financial instruments

As of September 30, 2019, the Company had $5.5 million of securities consisting of money market funds, commercial paper securities and U.S. government sponsored enterprise securities with maturities that range from four days to five months with an overall average time to maturity of approximately one month. The Company has the ability to liquidate these investments without restriction. The Company determines the fair value for securities with Level 1 inputs through quoted market prices. The Company determines the fair value for securities with Level 2 inputs through broker or dealer quotations or alternative pricing sources with reasonable levels of price transparency. The Company's Level 2 securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, typically utilizing third party pricing services or other observable market data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, and other industry and economic events. The Company's Level 3 inputs are unobservable inputs based on the Company's assessment that market participants would use in pricing the instruments.

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

	September 30, 2019	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 410	$ 410	$ —	$ —
Commercial paper	2,796	—	2,796	—
U.S. government sponsored enterprise securities	2,250	—	2,250	—
Total assets	$ 5,456	$ 410	$ 5,046	$ —
Liabilities:				
Warrant liability	$ 2,848	$ —	$ —	$ 2,848
Total liabilities	$ 2,848	$ —	$ —	$ 2,848

	December 31, 2018	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 20	$ 20	$ —	$ —
Commercial paper	9,729	—	9,729	—
U.S. government sponsored enterprise securities	2,198	—	2,198	—
Total assets	$ 11,947	$ 20	$ 11,927	$ —
Liabilities:				
Warrant liability	$ 1,399	$ —	$ —	$ 1,399
Total liabilities	$ 1,399	$ —	$ —	$ 1,399

Warrant liability

In connection with the offering completed on May 11, 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. The Company calculated the initial fair value of these warrants on May 11, 2016, the date the warrants were issued. As of September 30, 2019, only 10,000 of these warrants remain outstanding for which the fair value was remeasured as of September 30, 2019. The following inputs were utilized in the Black-Scholes pricing model:

	September 30, 2019	December 31, 2018
Stock price	$ 0.59	$ 0.83
Exercise price	$ 1.40	$ 1.40
Risk-free interest rate	1.67%	2.46%
Volatility	90.83%	82.47%
Dividend yield	0.00%	0.00%
Expected life in years	1.61	2.36
Calculated fair value per warrant	$ 0.13	$ 0.29

In connection with the offering completed on August 26, 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 Company calculated the initial fair value of these warrants on August 26, 2016, the date the warrants were issued. As of September 30, 2019, all of these warrants remain outstanding for which the fair value was remeasured. The following inputs were utilized in the Black-Scholes pricing model:

	September 30, 2019	December 31, 2018
Stock price	$ 0.59	$ 0.83
Exercise price	$ 4.00	$ 4.00
Risk-free interest rate	1.64%	2.45%
Volatility	86.81%	104.52%
Dividend yield	0.00%	0.00%
Expected life in years	1.90	2.65
Calculated fair value per warrant	$ 0.04	$ 0.25

In connection with the offering completed on August 29, 2019, the Company issued 5,333,334 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 Company calculated the initial fair value of these warrants on August 29, 2019, the date the warrants were issued. As of September 30, 2019, all of these warrants remain outstanding for which the fair value was remeasured. The following inputs were utilized in the Black-Scholes pricing model:

	Initial Fair Value Assessment August 29, 2019	September 30, 2019
Stock price	$ 0.78	$ 0.59
Exercise price	$ 0.95	$ 0.95
Risk-free interest rate	1.41%	1.56%
Volatility	126.36%	130.31%
Dividend yield	0.00%	0.00%
Expected life in years	5.51	5.42
Calculated fair value per warrant	$ 0.67	$ 0.49

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

	Warrant Liability
Liabilities:	
Balance at January 1, 2019	$ 1,399
Issuance of warrants on August 29, 2019	3,554
Change in the fair value of warrant liability	(2,105)
Balance at September 30, 2019	$ 2,848

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 and other current assets

Prepaid expenses and other current assets as of September 30, 2019 and December 31, 2018 consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Prepaid insurance	$ 507	$ 245
Prepaid research and development expenses	116	256
Other prepaid expenses and other current assets	87	155
Prepaid expenses and other current assets	$ 710	$ 656

As of September 30, 2019 and December 31, 2018, prepaid research and development expenses includes $34,000 and $0.2 million, respectively, for upfront fees paid to the Company's third-party manufacturing vendors for the development of topsalysin. The upfront fees will be relieved in future periods based upon work completed.

7. Accrued expenses

Accrued expenses as of September 30, 2019 and December 31, 2018 consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued personnel related costs	$ 221	$ 209
Accrued interest	31	41
Accrued research and development expenses	211	586
Accrued audit and tax services	238	168
Other accrued expenses	44	188
Accrued expenses	$ 745	$ 1,192

8. Promissory notes

On September 8, 2017, the Company entered into a new Loan and Security Agreement with Silicon Valley Bank, or SVB. Under the terms of the agreement, the Company borrowed $7.0 million which bears fixed interest of 6.75% per annum. The Company has the option to prepay the outstanding balance of the loan in full, subject to a prepayment fee of 1% to 3% depending upon when the prepayment occurs. Upon the final repayment of the loan on the maturity date of September 1, 2021, by prepayment, or upon acceleration, the Company will pay SVB an additional fee of 5% of the principal amount of $7.0 million. This additional fee was recorded as a debt discount and is being recognized as interest expense over the life of the loan utilizing the effective interest method.

Under the terms of the agreement, the Company had the option to request an additional $3.0 million of principal. The Company decided to not exercise the option to drawdown the additional $3.0 million of principal and this option expired at December 31, 2018.

In September 2018, the Company announced that it had met the requirements within its existing Loan and Security Agreement with SVB to extend the interest only periods to March 31, 2019. The Company began making interest and principal payments on April 1, 2019, with the final payment due on September 1, 2021.

Pursuant to the first tranche of the loan, the Company issued warrants to SVB to purchase an aggregate of up to 99,526 of the Company's common shares at an exercise price of $2.11 per share. The warrants expire on September 8, 2024. The fair value of $0.2 million for this equity component was derived using the Black-Scholes pricing model utilizing the following inputs: risk-free interest rate – 1.9%, volatility – 113.9%, dividend yield – 0% and expected life in years – 7. The $7.0 million proceeds were allocated to equity and the debt based on their relative fair values. The equity component was recognized as a debt discount and will be amortized to interest expense over the life of the debt. Interest on the loan, consisting of the stated interest rate, final payment fee and amortization of the discount, is being recognized under the effective interest method.

The third party issuance costs incurred related to the loan of $0.1 million are being amortized under the effective interest method over the life of the loan and have been recorded as a reduction to the loan balance.

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

The Company is not subject to any financial covenants under the loan. As of September 30, 2019, the Company was not in default under any of the provisions under the loan. The loan agreement contains customary affirmative and negative covenants, indemnification provisions and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain certain intellectual property rights. The negative covenants include, among others, restrictions on transferring or licensing our assets, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on our assets, in each case subject to customary exceptions. If the Company defaults under the loan, SVB may accelerate the loan and foreclose on the Company's pledged assets if the Company is unable to repay the loan in full. SVB could declare a default under the loan upon the occurrence of any event that SVB interprets as a material adverse change as defined under the loan agreement, thereby requiring us to repay the loan immediately.

As of September 30, 2019, the future contractual principal and final fee payments on our debt obligations are as follows (in thousands):

Remainder of 2019	$ 700
2020	2,800
2021	2,450
Total	$ 5,950

The following table shows actual interest expense, amortization of the debt discount and amortization of the issuance costs that was charged to interest expense (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Simple interest	$ 101	$ 121	$ 330	$ 358
Accretion of debt discount	32	38	101	113
Amortization of promissory note issuance costs	12	14	39	43
Total	$ 145	$ 173	$ 470	$ 514

The Company calculated the fair value of the secured promissory notes as $5.5 million (Level 3) as of September 30, 2019. The fair value of long-term debt is based on the net present value of calculated interest and principal payments, using an interest rate of 6.75%, which takes into consideration the financial position of the Company and the recent interest rate environment for new debt issuances for comparable companies. The fair value of this equity component was derived using the Black-Scholes valuation model. The Company calculated the promissory notes' fair value by allocating to equity and the debt based on their respective fair values.

9. Operating Lease

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2016-02, "Leases." ASU 2016-02 is intended to improve financial reporting of leasing transactions by requiring organizations that lease assets to recognize assets and liabilities for the rights and obligations created by leases on the balance sheet. The Company elected to adopt ASU 2016-02 retrospectively at January 1, 2019 using a simplified transition option that allows companies to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. We have also elected to adopt the package of practical expedients permitted in Accounting Standards Codification Topic 842, or ASC 842. Accordingly, the Company is continuing to account for our existing operating lease as operating leases under the new guidance, without reassessing whether the contracts contain a lease under ASC 842 or whether classification of the operating lease would be different under ASC Topic 842. The Company's lease at the adoption date was an operating lease for our corporate headquarters.

As a result of the adoption of ASU 2016-02, on January 1, 2019, the Company recognized (a) a lease liability of approximately $53,000, which represents the present value of our remaining lease payments using an estimated incremental borrowing rate of 6.75% and (b) a right-of-use asset of approximately $53,000. Due to the adoption of the standard using the retrospective cumulative-effect adjustment method, there are no changes to our previously reported results prior to January 1, 2019.

Effectively January 31, 2019, the Company elected to extend its existing facility lease for an additional 12 months which resulted in the extension of the Company's lease term from May 31, 2019 to May 31, 2020. As a result of this lease term extension the Company recognized a lease modification resulting in an increase to (a) a lease liability of approximately $124,000, which represents the present value of our remaining lease payments using an estimated incremental borrowing rate of 6.75% and (b) a right-of-use asset of approximately $124,000. As of September 30, 2019, the Company's lease liability and right-of-use assets was $85,000.

Total operating lease cost for the three and nine ended September 30, 2019 was $33,000 and $98,000, respectively. For the three and nine months ended September 30, 2019, $11,000 and $32,000 was included as a component of research and development expense and $22,000 and $66,000 was included as a component of general and administrative expense, respectively.

Maturity of the Company's lease liability is as follows (in thousands):

	September 30, 2019
Remainder of 2019	$ 33
2020	54
Total	87
Less interest	(2)
Present value of lease liability	$ 85

The remaining life of the Company's operating lease as of September 30, 2019 is eight months.

The discount rate of the Company's operating lease as of September 30, 2019 is 6.75%.

Future minimum lease payments under non-cancelable operating lease at December 31, 2018 was as follows (in thousands):

	December 31, 2018
2019	$ 130
2020	54
Total	$ 184

10. Shareholders' equity

On August 29, 2019, the Company completed a registered direct financing with a private institutional investor whereby it issued 3,355,000 common shares at a price of $0.75 per share and 1,978,334 pre-funded warrants to purchase common shares at an total price of $0.75 per share ($0.74 paid to the Company upon the closing of the offering and $0.01 to be paid upon exercise of the pre-funded warrants). In addition, the Company has also agreed to sell and issue warrants to purchase up to 5,333,334 common shares at an exercise price of $0.95 per share. The purchase warrants will be exercisable beginning on the six month anniversary of the date of issuance (the "Initial Exercise Date") and will expire on the fifth anniversary of the Initial Exercise Date. The Company received $3.6 million, net of underwriters' discounts and offering cost.

As multiple securities were issued in this transaction the proceeds from the transaction were allocated to each security based upon the calculated fair value of each security. The proceeds were first allocated to the calculated fair value of the common share purchase warrants. The remaining proceeds were then allocated to the common shares and pre-funded warrants based upon the relative fair value of each security. The pre-funded warrants are recorded as equity warrants and are included in contributed surplus. The common share purchase warrants are recorded as a liability and then marked to market each period through earnings in other income (expense) each period as the purchase warrants included in this transaction contain a "fundamental transaction" provision, which may in certain circumstances allow the common share purchase warrants to be redeemed for cash at an amount equal to the Black-Scholes Value, as defined by the warrant agreements. In addition, the warrants include a "failure to timely deliver shares" provision, which may require the Company to pay cash to the warrant holder in certain circumstances as defined by the warrant agreements. See a discussion on the calculation of the fair value associated with these warrants at Note 5.

In connection with this offering the Company incurred offering costs of approximately $0.4 million. The Company allocated these offering costs between the fair value of the common shares, the fair value of the pre-funded warrants and the fair value of the purchase warrants on the date of the closing. The Company allocated approximately $27,000 to the common shares and approximately $16,000 to the pre-funded warrants which was recorded as a reduction to shareholders equity. The remaining $0.4 million was allocated to the purchase warrants and expensed as a component of general and administrative expenses for the three and nine months ended September 30, 2019 as the purchase warrants are classified as liabilities.

On December 7, 2018, the Company entered into a Controlled Equity Offering^{SM} Sales Agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, as sales agent pursuant to which the Company may offer and sell from time to time, through Cantor Fitzgerald, common shares of the Company. On December 7, 2018, pursuant to the ATM Offering, the Company filed a prospectus supplement pursuant to which the Company may offer and sell, from time to time, Common Shares having an aggregate offering price of up to $20.0 million through Cantor, or the "ATM Prospectus Supplement". The Company will pay Cantor Fitzgerald an amount equal to 3.0% of the aggregate gross proceeds from each sale of common shares. No shares were issued under the Sales Agreement during the three months ended September 30, 2019. The Company terminated the ATM Prospectus Supplement on August 26, 2019, but the Sales Agreement remains in full force and effect.

11. 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. Historically the Company granted options with an exercise price denominated in Canadian dollars prior to the Company's U.S. IPO. Following the Company's U.S. IPO the Company has granted options with an exercise price denominated in U.S. dollars.

As of September 30, 2019, the Company has approximately 394,000 common shares which were available for issuance under the Plan.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 55	$ 38	$ 182	$ 142
General and administrative	135	219	422	535
Total	$ 190	$ 257	$ 604	$ 677

As of September 30, 2019, there was $0.4 million of total unrecognized compensation expense related to non-vested stock awards, which is expected to be recognized over a weighted average period of 1.1 years.

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

	Options Outstanding	Weighted Average Exercise Price
Outstanding at January 1, 2019	2,950	$ 1.60
Options granted	80	0.78
Options expired	(67)	2.65
Outstanding at September 30, 2019	2,963	$ 1.56

The fair values of options granted during the nine months ended September 30, 2019 and 2018 were estimated at the date of grant using the following weighted-average assumptions:

	Nine Months Ended September 30,	
	2019	2018
Expected life of the option term (years)	5.1	4.7
Risk-free interest rate	1.76%	2.67%
Dividend rate	0%	0%
Volatility	133.9%	126.2%

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 elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report, and the audited consolidated financial statements and notes as of and for the year ended December 31, 2018 included with our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 13, 2019. 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.

Overview

We are a clinical-stage biopharmaceutical company focused on developing innovative products for the treatment of urological diseases. We are headquartered in San Diego, California and our common shares currently trade on The Nasdaq 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 BPH, commonly referred to as an enlarged prostate. Topsalysin, a first-in-class, pore-forming protein, is a highly ablative agent that is selective and targeted in that it is only activated by enzymatically active prostate specific antigen, or PSA, which is found in high concentrations around prostate tumor cells and in the transition zone of the 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 PSA, which is found in high concentrations around prostate tumor cells and in the transition zone of the prostate, leading to localized cell death and tissue disruption without damage to neighboring tissue and nerves. This targeted method of administration limits the potential for systemic exposure of topsalysin, together with the specific mechanism of action, (topsalysin, is only activated by enzymatically active PSA which is found within the prostate, PSA in circulation is no longer enzymatically active) is thought to contribute the tolerability and safety profile observed to date.

We have completed a multicenter, open-label Phase 2b clinical trial to confirm the dose and optimize the delivery of topsalysin for the treatment of clinically significant localized prostate cancer. A total of 38 patients with a pre-identified clinically significant lesion, received a single administration of topsalysin at eight clinical trial sites located in the United Kingdom and United States. A review of the safety data from 38 patients, indicates that a single administration of topsalysin continues to appear safe and well-tolerated by patients. Adverse events considered related to topsalysin were typically mild and typically occurred and were resolved on the day of the administration. In addition, urine function was preserved, no sexual dysfunction, no hypersensitivity reactions or other serious systemic reactions to topsalysin were observed after a single administration.

A secondary objective of the trial was to evaluate the efficacy of a single administration of topsalysin to selectively target and focally ablate a pre-identified lesion. Six months after the administration of topsalysin, 37 out of 38 patients underwent a targeted biopsy of the treated lesion with one patient having been lost to follow-up following re-location. The six-month biopsy results demonstrated that, 27% of patients (10/37) achieved a clinical response, defined in this trial as no detectable tumor on targeted biopsy of the treated lesion or a sufficient reduction to deem the lesion clinically-insignificant (cancer lesion of Gleason Score 6 (pattern 3+3) and a maximum cancer core length, or MCCL, of less than 6 millimeters).

On June 19, 2019, we announced that we had received formal scientific advice from the European Medicines Agency, or EMA regarding a proposed design of a Phase 3 clinical trial to evaluate the potential of topsalysin as a targeted focal therapy to treat patients with intermediate risk localized prostate cancer. The Phase 3 trial design agree upon by the EMA would enroll patients with a confirmed diagnosis of intermediate risk disease. Approximately 700 men who meet the eligibility criteria will be equally randomized to receive a single administration of either topsalysin or placebo. The primary endpoint for the trial is the proportion of patients at 12 months who have failed treatment, defined as histological progression of disease, resulting in the need for alternative intervention, per an independent central adjudication panel. Based upon the feedback from the EMA, we believe that data from a single Phase 3 trial, if successful, should be sufficient to support market approval in Europe.

On October 21, 2019, we announced that following an End of Phase 2/ Pre-Phase 3 meeting with the United States Food and Drug Administration, or FDA, there is agreement regarding the design of a single Phase 3 clinical trial to evaluate the potential of topsalysin as a targeted focal therapy to treat patients with intermediate risk localized prostate cancer. The Phase 3 study design agreed upon with the FDA is consistent with the design previously agreed upon with the EMA. In addition, the FDA has indicated that in order to receive approval, we will need to evaluate all patients that progress to alternative treatments for an additional 12 months, for a total of 24 months of data, post the administration of the study drug.

Our goal is to conduct a single Phase 3 trial, which if successful, will provide the clinical data for approval in both the United States and Europe.

The scope of any additional trial in localized prostate cancer, including whether it will be a Phase 3 trial or an additional Phase 2 trial, will be dependent upon securing funding to finance such clinical trial. At this point in time, we do not plan on pursuing new clinical trials, including an additional trial in localized prostate cancer or a second Phase 3 trial in benign prostatic hyperplasia, or BPH, unless we secure a development partner to fund such new clinical trials or we obtain the necessary financing. We are currently evaluating options to further advance the clinical development of topsalysin. We will require significant additional funding to advance topsalysin in clinical development. We could use dilutive funding options such as an equity financing and/or non-dilutive funding options such as a partnering arrangement or other strategic arrangements to fund future clinical development of topsalysin. Any significant future public financing will most likely require the use of a Form S-1 registration statement. The process of getting a Form S-1 registration statement filed and declared effective can take an extended period of time which could delay the timing of any future significant financing. There can be no assurance that such funding will be secured in a timely manner or on favorable terms, if at all or that a development partner will be available on acceptable terms or if at all.

If we are unable to raise sufficient capital to fund our operations, we could be required to significantly reduce expenses, sell assets (potentially at a loss), cease operations altogether, file for bankruptcy or seek other protection from creditors, or liquidate all of our assets. We are also exploring partnership arrangements and other strategic alternatives which could include a merger or acquisition. See the Liquidity and Capital Resource section below for further details.

Further, we cannot currently estimate when the clinical development required to seek the regulatory approvals needed to commercialize topsalysin for the treatment of clinically significant localized prostate cancer or the treatment of the symptoms of BPH will be completed.

On August 29, 2019, we completed a registered direct financing whereby we issued 3,355,000 common shares at a price of $0.75 per share and 1,978,334 pre-funded warrants to purchase common shares at an total price of $0.75 per share ($0.74 paid to us upon the closing of the offering and $0.01 to be paid upon exercise of the pre-funded warrants). In addition, we have also agreed to sell and issue warrants to purchase up to 5,333,334 common shares at an exercise price of $0.95 per share. The purchase warrants will be exercisable beginning on the six-month anniversary of the date of issuance, or the “Initial Exercise Date” and will expire on the fifth anniversary of the Initial Exercise Date. We received $3.6 million, net of underwriters’ discounts and offering cost.

On March 7, 2019, we received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market LLC, or Nasdaq, notifying us that for the last 30 consecutive business days prior to the date of the letter, the market value of our listed securities was less than $35 million and therefore we did not meet the requirement for continued listing on The Nasdaq Capital Market as required by Nasdaq Listing Rule 5550(b)(2), or the Market Value Rule, or the alternative requirements under Nasdaq Listing Rules 5550(b)(1) and 5550(b)(3). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we had 180 calendar days, or until September 3, 2019, to regain compliance with the Market Value Rule.

On June 4, 2019, we received a letter from the Listing Qualifications Staff of Nasdaq notifying us that the closing bid price of our common shares had been below $1.00 per share for 30 consecutive business days and that we were therefore not in compliance with the minimum bid price requirement for continued listing on The Nasdaq Capital Market, as required by Nasdaq Listing Rule 5550(a)(2). Nasdaq stated in its June 4th letter that, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a grace period of 180 calendar days, or until December 2, 2019, to regain compliance with the minimum closing bid price requirement for continued listing. We will regain compliance if the closing bid price of our common shares is at or above $1.00 for at least 10 consecutive business days anytime during the 180-day grace period.

On September 6, 2019, we received a letter from the Nasdaq notifying us that we had not regained compliance with Market Value Rule by September 3, 2019 and as a result our securities will be delisted from the Nasdaq unless we requested an appeal of this determination. We formally requested an appeal of this determination on September 12, 2019. On October 17, 2019, we met with the Nasdaq Hearings Panel regarding our potential delisting from The Nasdaq Stock Market as a result of our failure to maintain a market value of our listed securities of at least $35 million or in the alternative to have more than $2.5 million in stockholders’ equity. On October 21, 2019, we received the Nasdaq Hearings Panel decision which granted us until January 24, 2020 to regain compliance with the listing standards of the Nasdaq Capital Market either by having the market value of our listed securities be at least $35 million during the preceding ten consecutive trading days before January 24, 2020, or having more than $2.5 million in stockholders’ equity by January 24, 2020. We will also be required to have a closing bid price of at least $1.00 per share during the preceding ten consecutive trading days before January 24, 2020. If we are unable to regain compliance with the listing standards of the Nasdaq Capital Market by January 24, 2020, our securities may be delisted from The Nasdaq Stock Market. As of the date of this filing we have not regained compliance with any of these listing rules.

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 of Kissei or any future collaborator, result in clinical success and regulatory approval or collaboration agreements with other third parties, we may generate revenues from 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;
- third-party manufacturing expenses;
- employee related expenses, including salaries, benefits, travel and stock-based compensation expense; 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 assuming we are able to obtain additional financing or secure a development partner to fund such 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 expenses and, in turn, have a material adverse effect on our results of operations.

Essentially all of our research and development expenses were related to topsalysin during the three and nine months ended September 30, 2019 and 2018. We recognized research and development expenses as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Clinical research and development	$ 383	$ 710	$ 1,223	$ 3,133
Manufacturing	300	1,050	1,977	5,443
Stock-based compensation expense	55	38	182	142
	$ 738	$ 1,798	$ 3,382	$ 8,718

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. However, if we were to move our drug candidate towards commercialization in future periods we would expect that general and administrative expenses would increase.

Interest Expense

Interest expense represents interest payable, amortization of our debt discount and issuance costs on our outstanding promissory notes.

Interest Income

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

Gain (Loss) on Revaluation of Warrant Liability

In connection with the offerings completed in 2016 and our recently completed registered direct financing on August 29, 2019, 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 pricing model 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 condensed 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, 2018 have the greatest potential impact on our financial statements, so we consider them to be our critical accounting policies and estimates.

Results Of Operations

Comparison of the three months ended September 30, 2019 and 2018

The following table summarizes the results of our operations for the three months ended September 30, 2019 and 2018, together with the changes in those items in dollars (in thousands):

	Three Months Ended September 30,		Change
	2019	2018	2019 vs. 2018
Research and development expenses	738	1,798	(1,060)
General and administrative expenses	1,388	1,155	233
Interest expense	(145)	(173)	28
Interest income	29	80	(51)
Gain on revaluation of warrant liability	1,281	153	1,128
Other income (expense)	2	21	(19)

Research and development expenses. Research and development expenses were $0.7 million in the three months ended September 30, 2019 compared to $1.8 million in the three months ended September 30, 2018. The decrease in research and development costs is attributable to the following:

- a $0.8 million decrease in the costs associated with manufacturing activities for topsalysin. During the three months ended September 30, 2018 we were actively pursuing a new drug product formulation and we were in the process of transferring our drug product manufacturing from Boehringer Ingelheim RCV GmbH & Co KG to Vetter Pharma International GmbH. Now that we have sufficient drug product on hand for future clinical trials, we expect that our costs associated with manufacturing activities will be less in future periods as we shift our focus to potential new clinical trials for topsalysin; and

- a $0.3 million decrease in clinical costs associated with our Phase 2b clinical trial of topsalysin for localized prostate cancer which was completed in late 2018.

Research and development expenses included non-cash stock-based compensation expenses of $55,000 for the three months ended September 30, 2019 as compared to $38,000 for the three months ended September 30, 2018.

General and administrative expenses. General and administrative expenses were $1.4 million in the three months ended September 30, 2019 as compared to $1.2 million for the three months ended September 30, 2018. Included as a component of general and administrative expense for the three months ended September 30, 2019 was $0.4 million of offering costs which were allocated to the common share purchase warrants issued in our August 2019 financing. These offering costs were allocated to general and administrative expense as the common share purchase warrants were classified as liabilities. General and administrative expenses included non-cash stock-based compensation expense of $0.1 million for the three months ended September 30, 2019 as compared to $0.2 million for the three months ended September 30, 2018.

Interest expense. Interest expense was $0.1 million in the three months ended September 30, 2019 as compared to $0.2 million for the three months ended September 30, 2018. The interest expense is related to our Silicon Valley Bank Loan and Security Agreement.

Interest income. Interest income was $29,000 for the three months ended September 30, 2019 as compared to $80,000 for the three months ended September 30, 2018. The decrease is due to the decrease in the average balances of interest-bearing cash and investment accounts from period to period.

Gain on revaluation of warrant liability. Gain on revaluation of the warrant liability was $1.3 million for the three months ended September 30, 2019 as compared to $0.2 million for the three months ended September 30, 2018. The 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.

Comparison of the nine months ended September 30, 2019 and 2018

The following table summarizes the results of our operations for the nine months ended September 30, 2019 and 2018, together with the changes in those items in dollars (in thousands):

	Nine Months Ended September 30,		Change
	2019	2018	2019 vs. 2018
Research and development expenses	3,382	8,718	(5,336)
General and administrative expenses	3,858	3,494	364
Interest expense	(470)	(514)	44
Interest income	133	258	(125)
Gain on revaluation of warrant liability	2,105	143	1,962
Other income (expense)	(11)	27	(38)

Research and development expenses. Research and development expenses were $3.4 million for the nine months ended September 30, 2019 compared to $8.7 million for the nine months ended September 30, 2018. The decrease in research and development costs is attributable to the following:

- a $3.5 million decrease in the costs associated with manufacturing activities for topsalysin. During the nine months ended September 30, 2019 we completed a fill finish campaign which produced drug product for future clinical trials. During the nine months ended September 30, 2018 we were actively pursuing a new drug product formulation and we were in the process of transferring our drug product manufacturing from Boehringer Ingelheim RCV GmbH & Co KG to Vetter Pharma International GmbH. Now that we have sufficient drug product on hand for future clinical trials, we expect that our costs associated with manufacturing activities will be less in future periods as we shift our focus to potential new clinical trials for topsalysin; and

- a $1.8 million decrease in clinical costs associated with our Phase 2b clinical trial of topsalysin for the treatment of localized prostate cancer which completed in late 2018.

Research and development expenses included non-cash stock-based compensation expenses of $0.2 million for the nine months ended September 30, 2019 as compared to $0.1 million for the nine months ended September 30, 2018.

General and administrative expenses. General and administrative expenses were $3.9 million for the nine months ended September 30, 2019 compared to $3.5 million for the nine months ended September 30, 2018. Included as a component of general and administrative expense for the nine months ended September 30, 2019 was $0.4 million of offering costs which were allocated to the common share purchase warrants issued in our August 2019 financing. These offering costs were allocated to general and administrative expense as the common share purchase warrants were classified as liabilities. General and administrative expenses included non-cash stock-based compensation expense of $0.4 million for the nine months ended September 30, 2019 as compared to $0.5 million for the nine months ended September 30, 2018.

Interest expense. Interest expense was $0.5 million for the nine months ended September 30, 2019 and 2018. Interest expense is related to our Silicon Valley Bank Loan and Security Agreement.

Interest income. Interest income was $0.1 million for the nine months ended September 30, 2019 compared to $0.3 million for the nine months ended September 30, 2018. The decrease is due to the decrease in the average balances of interest-bearing cash and investment accounts from period to period.

Gain on revaluation of warrant liability. Gain on revaluation of the warrant liability was $2.1 million for the nine months ended September 30, 2019 as compared to $0.1 million for the nine months ended September 30, 2018. The 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.

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.

On August 29, 2019, we completed a registered direct financing whereby we issued 3,355,000 common shares at a price of $0.75 per share and 1,978,334 pre-funded warrants to purchase common shares at an total price of $0.75 per share ($0.74 paid to us upon the closing of the offering and $0.01 to be paid upon exercise of the pre-funded warrants). In addition, we have also agreed to sell and issue warrants to purchase up to 5,333,334 common shares at a price of $0.95 per share. The purchase warrants will be exercisable beginning on the six-month anniversary of the date of issuance, or the “Initial Exercise Date” and will expire on the fifth anniversary of the Initial Exercise Date. We received $3.6 million, net of underwriters’ discounts and offering cost.

The condensed consolidated financial statements have been prepared assuming we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. We have incurred net losses from operations since inception, including $5.5 million in the nine months ended September 30, 2019 and has an accumulated deficit of $161.8 million as of September 30, 2019. At September 30, 2019, we had cash, cash equivalents and securities available-for-sale of $6.3 million. As of September 30, 2019, the future principal and final fee payments under the Loan and Security Agreement with SVB total $6.0 million. The maturity date of the loan is September 1, 2021. We are currently paying monthly installments of principal and interest under the Loan and Security Agreement. However, if we fail to make principal and interest payments when due or another event of default occurs under the loan, SVB may accelerate the loan and foreclose on our pledged assets if we are unable to repay the loan in full. Events of default include the occurrence of a material adverse change as defined in the Loan and Security Agreement. As of the date of filing of this Form 10-Q, we are not in default under any of the provisions of the Loan and Security Agreement. We expect that our cash, cash equivalents and securities available-for-sale will be sufficient to fund our operations and debt service through March 2020 (assuming no acceleration of the loan) and, as a result, there is substantial doubt about our ability to continue as a going concern for one year from the date of the issuance of our condensed consolidated financial statements for the nine months ended September 30, 2019.

We announced that we have received formal scientific advice from the EMA and reached an agreement with the FDA regarding a design for a single Phase 3 clinical trial to evaluate the potential of topsalysin as a targeted focal therapy to treat patients with intermediate risk localized prostate cancer. Based upon feedback from the EMA and the FDA, we believe that data from a single Phase 3 trial, if successful, should be sufficient to support market approval in both the U.S. and Europe. The scope of any additional trial in localized prostate cancer, including whether it will be a Phase 3 trial or an additional Phase 2 trial, will be dependent upon securing funding to finance such clinical trial. At this point in time, we do not plan on pursuing new clinical trials, including an additional trial in localized prostate cancer or a second Phase 3 trial in benign prostatic hyperplasia, or BPH, unless we secure a development partner to fund such new clinical trials or it obtains the necessary financing. We are currently evaluating options to further advance the clinical development of topsalysin. We will require significant additional funding to advance topsalysin in clinical development. We could use dilutive funding options such as an equity financing and/or non-dilutive funding options such as a partnering arrangement or other strategic arrangements to fund future clinical development of topsalysin. Any significant future public financing will most likely require the use of a Form S-1 registration statement. The process of getting a Form S-1 registration statement filed and declared effective can take an extended period of time which could delay the timing of any future significant financing. There can be no assurance that such funding will be secured in a timely manner or on favorable terms, if at all or that a development partner will be available on acceptable terms or if at all.

If we are unable to raise sufficient capital to fund our operations, we could be required to significantly reduce expenses, sell assets (potentially at a loss), cease operations altogether, file for bankruptcy or seek other protection from creditors, or liquidate all of our assets. We are also exploring partnership arrangements and other strategic alternatives which could include a merger or acquisition.

On March 7, 2019, we received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market LLC, or Nasdaq, notifying us that for the last 30 consecutive business days prior to the date of the letter, the market value of our listed securities was less than $35 million and therefore we did not meet the requirement for continued listing on The Nasdaq Capital Market as required by Nasdaq Listing Rule 5550(b)(2), or the Market Value Rule, or the alternative requirements under Nasdaq Listing Rules 5550(b)(1) and 5550(b)(3). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we had 180 calendar days, or until September 3, 2019, to regain compliance with the Market Value Rule. We will regain compliance with the Market Value Rule if the market value of our listed securities closes at or above $35 million for a minimum of 10 consecutive business days anytime during the 180 day compliance period. As of the date of this prospectus supplement we have not regained compliance with the Market Value Rule.

On June 4, 2019, we received a letter from the Listing Qualifications Staff of Nasdaq notifying us that the closing bid price of our common shares had been below $1.00 per share for 30 consecutive business days and that we were therefore not in compliance with the minimum bid price requirement for continued listing on The Nasdaq Capital Market, as required by Nasdaq Listing Rule 5550(a)(2). Nasdaq stated in its June 4th letter that, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a grace period of 180 calendar days, or until December 2, 2019, to regain compliance with the minimum closing bid price requirement for continued listing. We will regain compliance if the closing bid price of our common shares is at or above $1.00 for at least 10 consecutive business days anytime during the 180-day grace period. As of the date of this filing we have not regained compliance with this rule.

On September 6, 2019, we received a letter from the Nasdaq notifying us that we had not regained compliance with Market Value Rule by September 3, 2019 and as a result our securities will be delisted from the Nasdaq unless we requested an appeal of this determination. We formally requested an appeal of this determination on September 12, 2019. On October 17, 2019, we met with the Nasdaq Hearings Panel regarding our potential delisting from The Nasdaq Stock Market as a result of our failure to maintain a market value of our listed securities of at least $35 million or in the alternative to have more than $2.5 million in stockholders' equity. On October 21, 2019, we received the Nasdaq Hearings Panel decision which granted us until January 24, 2020 to regain compliance with the listing standards of the Nasdaq Capital Market either by having the market value of our listing securities of at least $35 million during the preceding ten consecutive trading days or having more than $2.5 million in stockholders' equity. We will also be required to have a closing bid price of at least $1.00 per share during the preceding ten consecutive trading days before January 24, 2020. If we are unable to regain compliance with the listing standards of the Nasdaq Capital Market by January 24, 2020, our securities may be delisted from The Nasdaq Stock Market. As of the date of this filing we have not regained compliance with any of these listing rules.

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 future clinical trials, 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 nine months ended September 30, 2019 and 2018 (in thousands):

	Nine Months Ended September 30	
	2019	2018
Net cash provided by (used in):		
Operating activities	$ (8,427)	$ (11,341)
Investing activities	(482)	7,302
Financing activities	2,162	—
Net (decrease) increase in cash and cash equivalents	$ (6,747)	$ (4,039)

Operating Activities

Net cash used in operating activities decreased to $8.4 million for the nine months ended September 30, 2019 compared to $11.3 million for the nine months ended September 30, 2018. The decrease in net cash used in operating activities of $2.9 million was primarily due to the decrease in our net loss from period to period which was offset by an increase in funds used for the payment of accounts payable and accrued expenses in the nine months period ended September 30, 2019. The decrease in the net loss is due to a reduction in costs associated with our manufacturing activities for topsalysin, a reduction in our clinical trial costs associated with our completed Phase 2b localized prostate cancer clinical trial and the increase in the non-cash gain recorded for the revaluation of our warrant liability from period to period.

Investing Activities

Net cash used in investing activities was $0.5 million for the nine months ended September 30, 2019, compared to net cash provided by investing activities of $7.3 million for the nine months ended September 30, 2018. The net cash (used in) and provided by investing activities during the nine months ended September 30, 2019 and 2018 represents the use of securities classified as available-for-sale or proceeds from the maturity of securities classified as available-for-sale.

Financing Activities

Net cash provided by financing activities was $2.2 million for the nine months ended September 30, 2019. The net cash provided by financing activities is primarily related to our registered direct financing with a private institutional investor. We received $3.7 million of proceeds, net of paid issuance costs. This increase is offset by principal payments on our Silicon Valley Bank Loan and Security Agreement and payments for offering costs associated with the establishment of our Controlled Equity and Sales Agreement℠ with Cantor Fitzgerald & Co.

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.

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, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, 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 September 30, 2019, 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 under the Exchange Act. Based on this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2019.

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 the quarter ended September 30, 2019 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 SEC on March 13, 2019.

Risks Related to Our Business and Industry

We will require significant funding to fund our operations, and there is substantial doubt about our ability to continue as a going concern.

Our Annual Report on Form 10-K for the year ended December 31, 2018 includes disclosures regarding management's assessment of our ability to continue as a going concern and a report from our independent registered public accounting firm that includes an explanatory paragraph regarding going concern, as there is substantial doubt about our ability to continue as a going concern due to our current liquidity position and recurring losses from operations since inception and negative cash flows from operating activities.

The condensed consolidated financial statements have been prepared assuming we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. We have incurred net losses from operations since inception, including $5.5 million in the nine months ended September 30, 2019, and have an accumulated deficit of $161.8 million as of September 30, 2019. On August 29, 2019, we completed a registered direct financing with a private institutional investor whereby we received $3.6 million, net of underwriters' discounts and offering costs. At September 30, 2019, we had cash, cash equivalents and securities available-for-sale of $6.3 million. As of September 30, 2019, the future principal and final fee payments under the Loan and Security Agreement with Silicon Valley Bank, or SVB, totaled $6.0 million. The maturity date of the loan is September 1, 2021. We are currently paying monthly installments of principal and interest under the Loan and Security Agreement. However, if we fail to make principal and interest payments when due or another event of default occurs under the loan, SVB may accelerate the loan and foreclose on our pledged assets if we are unable to repay the loan in full. Events of default include the occurrence of a material adverse change as defined in the Loan and Security Agreement. As of the date of filing of this Form 10-Q, we are not in default under any of the provisions of the Loan and Security Agreement. We expect that our cash, cash equivalents and securities available-for-sale will be sufficient to fund our operations and debt service through March 2020 (assuming no acceleration of the loan) and, as a result, there is substantial doubt about our ability to continue as a going concern for one year from the date of the issuance of our condensed consolidated financial statements for the nine months ended September 30, 2019.

Our operations have consumed substantial amounts of cash since inception. Since inception, we have raised approximately $149 million from the sale of equity securities in private placements and public offerings, $28 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 announced that we had received formal scientific advice from the European Medicines Agency, or EMA, and reached an agreement with the U.S. Food and Drug Administration, or FDA, regarding a design for a single Phase 3 clinical trial to evaluate the potential of topsalysin as a targeted focal therapy to treat patients with intermediate risk localized prostate cancer. Based upon feedback from the EMA and the FDA, we believe that data from a single Phase 3 trial, if successful, should be sufficient to support market approval in both the U.S. and Europe. The scope of any additional trial in localized prostate cancer, including whether it will be a Phase 3 trial or an additional Phase 2 trial, will be dependent upon securing funding to finance such clinical trial. At this point in time, we do not plan on pursuing new clinical trials, including an additional trial in localized prostate cancer or a second Phase 3 trial in benign prostatic hyperplasia, or BPH, unless we secure a development partner to fund such new clinical trials or we obtain the necessary financing. We are currently evaluating options to further advance the clinical development of topsalysin. We will require significant additional funding to advance topsalysin in clinical development. We could use dilutive funding options such as an equity financing and/or non-dilutive funding options such as a partnering arrangement or other strategic arrangements to fund future clinical development of topsalysin. Any significant future public financing will most likely require the use of a Form S-1 registration statement. The process of getting a Form S-1 registration statement filed and declared effective can take an extended period of time which could delay the timing of any future significant financing. There can be no assurance that such funding will be secured in a timely manner or on favorable terms, if at all or that a development partner will be available on acceptable terms or if at all.

If we are unable to raise sufficient capital to fund our operations, we could be required to significantly reduce expenses, sell assets (potentially at a loss), cease operations altogether, file for bankruptcy or seek other protection from creditors, or liquidate all of our assets. We are also exploring partnership arrangements and other strategic alternatives which could include a merger or acquisition. Furthermore, if there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

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 a development stage company with no approved products and no revenue from commercialization of any products.

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. Topsalysin requires significant additional clinical testing and investment prior to seeking marketing approval for either the treatment of localized prostate cancer or as a treatment for the lower urinary tract symptoms of BPH. 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 in this indication. At this point in time we have no immediate plans to conduct a second Phase 3 trial in BPH unless we secure a development partner to fund such new clinical trials or obtain financing in excess of the financing required for our prostate cancer development program, which is our development priority.

We are planning a clinical trial of topsalysin for the treatment of patients with clinically significant localized prostate cancer. Our goal is to conduct a single Phase 3 trial, which if successful, will provide the clinical data for approval in both the US and Europe. In addition, the scope of any additional trial in localized prostate cancer, including whether it will be a Phase 3 clinical trial or an additional Phase 2 trial will be dependent upon securing sufficient funding to finance such clinical trial. Any delay in the finalization of the design and funding of the next clinical study would delay our development of topsalysin for the treatment of localized prostate cancer.

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 treatment of clinically significant localized prostate cancer and for the treatment of lower urinary tract symptoms of BPH, 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 topsalysin program 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 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 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.

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.” 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. In our completed Phase 2b localized prostate cancer trial a single administration of topsalysin continues to appear safe and well tolerated by patients. No hypersensitivity reactions or other serious systemic reactions to topsalysin were observed after a single administration. Adverse events considered related to topsalysin and occurring in more than one patient were: dysuria (3 patients), urinary retention (3 patients), proctalgia (2 patients), perineal pain (2 patients), nocturia (2 patients), micturition urgency (2 patients) and strangury (2 patients). All adverse events were considered mild and typically resolved within the same day. One event of micturition urgency was considered severe and resolved the same day, two events were considered moderate in severity, one event of perineal pain which resolved within a day and one event of urinary retention was considered moderate and the event was considered resolved after the patient underwent a transurethral resection of the prostate. One of the topsalysin related mild events of strangury was reported as a serious adverse event (SAE) because the patient was hospitalized overnight for monitoring as was the practice at the site in the United Kingdom where the patient had been treated. The event of strangury resolved the next day and the patient was released from the hospital.

In August 2018, we announced that we had completed an investigation into the death of a patient in the Phase 2b trial for the treatment of localized prostate cancer. It was concluded that the patient death was unlikely to be related to either topsalysin or the injection procedure. On December 17, 2018, we announced the interim safety and tolerability results from the 10 patients who received a second administration of topsalysin from our completed Phase 2b localized prostate cancer trial. A second administration of topsalysin appears to be both safe and well-tolerated by patients. There were no adverse events considered related to topsalysin that were experienced by more than one patient following the second administration. The adverse events that were considered related to topsalysin were typically mild and resolved within two days. Importantly, no hypersensitivity reaction or other serious systemic reactions to topsalysin were observed. Urine function was preserved and there were no reports of sexual dysfunction related to topsalysin.

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 localized 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.

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 either lower urinary tract symptoms of BPH or clinically significant localized prostate cancer or demonstrate safety or efficacy at the level required by the FDA for product approval in either indication.

Our initial Phase 3 clinical trial for 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 received formal scientific advice from the EMA and reached an agreement with FDA regarding a design for a single Phase 3 clinical trial to evaluate the potential of topsalysin as a targeted focal therapy to treat patients with intermediate risk localized prostate cancer. Based upon feedback from the EMA and the FDA,we believe that data from a single Phase 3 trial, if successful, should be sufficient to support market approval in both the U.S. and Europe. However, this advice and agreement are not binding on the regulatory agencies, and 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 BPH trial and any future Phase 3 clinical trials has or will generate data sufficient to establish the effectiveness of topsalysin for treatment for either indication to the FDA's satisfaction, and therefore allow us to submit or receive approval of a Biologics License Application, or BLA for topsalysin in either indication.

Specifically, with respect to our development of topsalysin for the treatment of BPH symptoms, the FDA has not agreed upon the amount of IPSS treatment effect that must be demonstrated in our Phase 3 clinical trials of topsalysin in order for it to grant marketing approval for the treatment of BPH symptoms. Historically, oral medications for the treatment of BPH have shown approximately a 2 point improvement in IPSS between active and control, which was not seen in our PLUS-1 clinical trial. 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 in this indication could be delayed 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 either or both indications.

Our clinical trials may fail to adequately demonstrate safety and efficacy of topsalysin for either indication being pursued which 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.

****We rely on third parties to manufacture 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 topsalysin 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 commercial scale. Instead, we rely on our third-party manufacturing partners. Although we have entered into agreements for the manufacture of clinical supplies of topsalysin, our third party manufacturing partners may not perform as agreed, may be unable to comply with cGMP requirements and with FDA, state and foreign regulatory requirements or may terminate their agreements with us. We do not control the manufacturing processes of our third party manufacturers and we are completely dependent on our third party manufacturers 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. Our purchase orders under our manufacturing contracts either cannot be cancelled or can only be cancelled with the payment of financial penalties.

We have entered into an agreement with Boehringer Ingelheim RCV GmbH & Co KG, or BI, to manufacture topsalysin drug substance. We have completed scale-up up to the commercial scale for topsalysin drug substance. In addition, we recently completed a project to optimize the formulation of topsalysin drug product. We have incurred significant costs to ensure that the optimised drug product formulation is biochemically and biophysically comparable to our previous drug product formulation. There is no guarantee that the new drug product formulation will obtain the same clinical results as our old drug formulation.

We have entered into a long-term agreement with Vetter Pharma International GmbH, or Vetter, to work on the commercial fill finish process for the production of reformulated topsalysin drug product and to supply clinical trial drug product material. We have incurred significant costs in connection with the technology transfer and manufacturer of clinical drug supplies. During the first quarter of 2019, we completed a fill finish campaign at commercial scale which produced drug product for future clinical trials. Analysis for release of this recently filled drug product is underway. Any delay in the release of this clinical trial drug product would result in future delays in our ability to commence additional clinical trials.

BI historically procured an ingredient used in our former diluent formulation for use with topsalysin drug product from a multinational industrial biotech company which is a single source supplier, on a purchase order basis. Our new drug product formulation does not use this single source provider ingredient in the diluent formulation. If we are required to revert back to our old drug product formulation and 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.

If our third-party manufacturers 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 manufacturers 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 manufacturers 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.

The facilities used by our third-party manufacturers 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. Further, 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 manufacturers are located outside the United States and the FDA has recently increased the number of foreign drug manufacturers which it inspects. As a result, these third-party manufacturers may be subject to increased scrutiny.

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. Also, if we were to experience an unexpected loss of topsalysin supply, we could experience delays in our future clinical trials as our third party manufacturers 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 a facility at the same time as other biologics.

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 contaminants 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 was 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 may seek a partner for the continued development and commercialization of topsalysin. If we seek a partner and are unable to find a partner or such partnership is unsuccessful, we may be unable to commercialize topsalysin.

We may seek a third-party partner for financial and scientific resources for the further clinical development and commercialization of topsalysin. 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 and/or commercialization 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 or as a treatment for clinically significant localized prostate cancer 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 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.

Further, if a partnership terminates an agreement with us 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 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 28 member states of the European Union plus Norway, Liechtenstein and Iceland, we must submit a Marketing Authorization Application, or MAA, to the 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 is 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.

Delays in the commencement or completion of clinical testing could significantly impact our product development costs and will delay our ability to pursue regulatory approval and, in turn, our ability to generate any product revenues.

Although we have completed the first of two required Phase 3 clinical trials of topsalysin for the treatment for the lower urinary tract symptoms of BPH and completed a Phase 2b open-label clinical trial for the treatment of localized low to intermediate risk 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 future clinical trials, including a Phase 3 clinical trial of topsalysin for the treatment of clinically significant localized prostate cancer and a second Phase 3 clinical trial for the treatment of the symptoms of BPH;
- 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;
- 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 for the treatment of the lower urinary tract symptoms of BPH unless we secure a development partner to fund such clinical trial or we obtain financing in excess of the financing required for our localized prostate cancer development program, which is our development priority.

We may face competition to enroll localized 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 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 have relied upon and expect to rely upon multiple CROs to conduct and oversee 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 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 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. Kissei is not currently conducting any clinical trials with topsalysin for the treatment of BPH, prostate cancer, prostatitis or other diseases of the prostate.

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, laser ablation and TOOKAD, a vascular –targeted photodynamic therapy recently approved by the EMA. In addition, in January 2018, Nymox Pharmaceuticals announced top-line five year clinical trial biopsy data from the intraprostatic administration of their investigational therapy NX-1207 (fexapotide triflutate) in patients with low grade localized (T1c) prostate cancer.

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. 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. 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. Nymox Pharmaceuticals announced that it plans to submit a New Drug Application for Fexapotide Triflutate for the treatment of BPH in the United States. In December 2017, Procept BioRobotics received FDA clearance for its AquaBeam System, a waterjet ablation therapy for endoscopic resection of prostate tissue. 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 talaporfin sodium is currently in Phase 2 clinical trials.

The availability and price of our competitors' products and procedures could limit the demand, and the price we are able to charge, for topsalysin. Further, our lack of data on long term disease progression 5 to 10 years following administration of topsalysin in order to demonstrate that our product is comparable to more radical therapies such as prostatectomy and/or radiation could limit demand for topsalysin for focal treatment of localized prostate cancer. 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. 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. 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. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. 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 federal legislation, manufacturers are 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 federal and state 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 significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal healthcare programs, and additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, 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 September 30, 2019, we had six full-time employees. In addition, we had engaged three part-time individual consultants to assist us with managing manufacturing vendors and CROs, project management, legal and regulatory compliance. We will need to expand our managerial, operational, financial and other resources in order to manage our future 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.

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

In September 2017, we entered into a Loan and Security Agreement with SVB. This loan is secured by a lien covering all of our assets, excluding intellectual property, and we also pledged as collateral all of our equity interests in Sophiris Bio Corp. and Sophiris Bio Holding Corp.

While any amounts are outstanding under the Loan and Security Agreement, we are subject to a number of affirmative and restrictive covenants, including covenants regarding dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness and transactions with affiliates, among other customary covenants. We are also restricted from paying dividends or making other distributions or payments on our capital stock, subject to limited exceptions. Upon the occurrence of an event of default by us under the Loan and Security Agreement, SVB will have customary acceleration, collection and foreclosure remedies.

Further, if we are liquidated, SVB's right to repayment would be senior to the rights of the holders of our common shares to receive any proceeds from the liquidation. SVB could declare a default under the loan upon the occurrence of any event that SVB interprets as a material adverse change as defined under the loan agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by SVB of an event of default could significantly harm our business and prospects and could cause the price of our common shares to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Our ability to generate revenues from topsalysin will be subject to obtaining 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 procedures or drugs;
- efficacy and safety of topsalysin and the availability of data to demonstrate long-term efficacy;
- the clinical indication(s) for which topsalysin is approved;
- continued projected growth of the urological disease markets, including incidence of localized prostate cancer with tumors amenable to focal therapy, and incidence of BPH;
- continued adoption and improvement of imaging and diagnostic tools, including MRI-guided biopsies and molecular tests, to assess and identify candidates for focal treatment of localized prostate cancer;

- acceptance by patients, primary care specialists and key specialists, including urologists and oncologists for localized prostate cancer and urologists for BPH;
- potential or perceived advantages or disadvantages of topsalysin over alternative treatments, for prostate cancer and BPH including cost of treatment and relative convenience and ease of administration, the amount of time for a patient to notice the effects of the treatment 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 reimbursement and pricing from government and other third-party payors for MRI-guided biopsies and other diagnostic tools and for topsalysin procedures; 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 coverage and 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 changed the way healthcare is financed by both governmental and private insurers and significantly affected the pharmaceutical industry. Among the provisions of the PPACA of greatest importance to the pharmaceutical industry are that it: (i) created 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) increased 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) created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% 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) extended of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (v) expanded 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) expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; (vii) expanded health care fraud and abuse laws, including the federal civil False Claims Act and the federal healthcare anti-kickback statute, new government investigative powers, and enhanced penalties for noncompliance; and (viii) created 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 certain aspects of the PPACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, the Centers for Medicare & Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA and our business. Congress may consider other legislation to replace elements of the PPACA.

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 BBA, will remain in effect through 2027 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 in the United States over the manner in which drug manufacturers set prices for their marketed products, in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. On January 31, 2019, the U.S. Department of Health and Human Services, Office of Inspector General, proposed modifications to the federal health care program anti-kickback statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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.

We are dependent on information technology systems, infrastructure and data, which exposes us to data security risks.

We are dependent upon our own or third-party information technology systems, infrastructure and data, including mobile technologies, to operate our business. The multitude and complexity of our computer systems may make them vulnerable to service interruption or destruction, disruption of data integrity, malicious intrusion, or random attacks. Likewise, data privacy or security incidents or breaches by employees or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity. Cyber-attacks could include the deployment of harmful malware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Our business partners face similar risks and any security breach of their systems could adversely affect our security posture. A security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to litigation or other liability under laws and regulations that protect personal data, any of which could disrupt our business and/or result in increased costs or loss of revenue. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

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 manufacturers 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 these third party manufacturers 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 manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturers' 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 manufacturers 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 manufacturers 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. Our third-party manufacturers, do 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 manufacturers' 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. and multiple outside consultants. 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. 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, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, 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 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.

****Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to our Financial Position and Capital Requirements

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 $5.5 million during the nine months ended September 30, 2019 and $6.8 million, $8.6 million, and $11.2 million during the years ended December 31, 2018, 2017 and 2016, respectively. As of September 30, 2019 and December 31, 2018, we had an accumulated deficit of $161.8 and $156.3 million, respectively. 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 clinically significant localized prostate cancer and as a treatment for the lower urinary tract symptoms of BPH. In addition, if we obtain regulatory approval of topsalysin in either indication, 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 a development milestone, 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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, the president of the United States signed into law the Tax Act that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

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

We currently incur expenses denominated in foreign currencies for multiple vendors. This includes our manufacturing and supply agreements for the manufacture of topsalysin, for which payments are denominated in foreign currency. 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 nine months ended September 30, 2019 and 2018, 27.0% and 46.6% 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 Finance LLC, or Oxford, with the U.S. PTO or foreign jurisdictions in 2011 in connection with our Oxford Loan and Security Agreement 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 outstanding balance under the Oxford Loan and Security Agreement 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

If we fail to satisfy applicable listing standards, our common shares may be delisted from The Nasdaq Capital Market.

On March 7, 2019, we received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market LLC, or Nasdaq, notifying us that for the last 30 consecutive business days prior to the date of the letter, the market value of our listed securities was less than $35 million and therefore we did not meet the requirement for continued listing on The Nasdaq Capital Market as required by Nasdaq Listing Rule 5550(b)(2), or the Market Value Rule, or the alternative requirements under Nasdaq Listing Rules 5550(b)(1) and 5550(b)(3). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we had 180 calendar days, or until September 3, 2019, to regain compliance with the Market Value Rule.

On June 4, 2019, we received a letter from the Listing Qualifications Staff of Nasdaq notifying us that the closing bid price of our common shares had been below $1.00 per share for 30 consecutive business days and that we were therefore not in compliance with the minimum bid price requirement for continued listing on The Nasdaq Capital Market, as required by Nasdaq Listing Rule 5550(a)(2). Nasdaq stated in its June 4th letter that, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a grace period of 180 calendar days, or until December 2, 2019, to regain compliance with the minimum closing bid price requirement for continued listing. We will regain compliance if the closing bid price of our common shares is at or above $1.00 for at least 10 consecutive business days anytime during the 180-day grace period.

On September 6, 2019, we received a letter from Nasdaq notifying us that we had not regained compliance with the Market Value Rule by September 3, 2019 and as a result that our securities would be delisted from The Nasdaq Capital Market unless we requested an appeal of this determination. We formally requested an appeal of the determination on September 12, 2019. On October 17, 2019, we met with the Nasdaq Hearings Panel regarding our potential delisting from The Nasdaq Stock Market as a result of our failure to maintain a market value of our listed securities of at least $35 million or in the alternative to have more than $2.5 million in stockholders' equity. On October 21, 2019, we received the Nasdaq Hearings Panel decision which granted us until January 24, 2020 to regain compliance with the listing standards of The Nasdaq Capital Market, by either having the market value of our listed securities be at least $35 million during the preceding 10 consecutive trading days before January 24, 2020 or having more than $2.5 million in stockholders' equity by January 24, 2020. We will also be required to have a closing bid price of at least $1.00 per share during the preceding 10 consecutive trading days before January 24, 2020. If we are unable to regain compliance with the listing standards of The Nasdaq Capital Market by January 24, 2020, our securities may be delisted from The Nasdaq Stock Market. As of the date of this filing we have not regained compliance with any of these listing rules.

There is no guarantee that we will be able to regain compliance with the Nasdaq listing standards requirements or the minimum bid price requirement, either of which could result in Nasdaq taking steps to delist our common shares. Delisting from The Nasdaq Capital Market could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common shares. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. If our common shares are delisted by The Nasdaq Capital Market, the price of our common shares may decline, and although our common shares may be eligible to trade on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets, an investor may find it more difficult to dispose of their common shares or obtain accurate quotations as to the market value of our common shares. Further, if we are delisted, we would incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common shares and the ability of our shareholders to sell our common shares in the secondary market.

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 through 2017 and that we will likely be a PFIC for the taxable year ending December 31, 2018. In 2019 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 initial public offering, or IPO, in our business and other factors. If we are a PFIC for the taxable year ending December 31, 2018 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 were 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, 2018 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 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, particularly now that 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.

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;
- changes in the structure of healthcare payment systems;

- 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.

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 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. Our Loan and Security Agreement with SVB also contains a negative covenant which prohibits us from paying dividends without the prior written consent of SVB. Any return to shareholders will therefore be limited to the increase, if any, of our share price.

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 Registrant, dated January 1, 2005.	Incorporated by reference to Exhibit 3.1 to the Registrant's Form S-1 (SEC File No. 333-186724) filed on February 15, 2013.
3.2	Notice of Articles of the Registrant.	Incorporated by reference to Exhibit 3.2 to the Quarterly Report on Form 10-Q filed on August 10, 2017.
3.3	Articles of the Registrant.	Incorporated by reference to Exhibit 3.3 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 Exhibit 4.1 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 dated June 30, 2014.	Incorporated by reference to Exhibit 4.10 to the Quarterly Report on Form 10-Q filed on August 7, 2014 (SEC File No. 001-36054).
4.3	Common Share Purchase Warrant Issued to Oxford Finance LLC dated June 30, 2014.	Incorporated by reference to Exhibit 4.11 to the Quarterly Report on Form 10-Q filed on August 7, 2014 (SEC File No. 001-36054).
4.4	Form of Common Share Purchase Warrant Issued in connection with the Registrant's May 2016 Financing.	Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on May 11, 2016.
4.5	Form of Common Share Purchase Warrant Issued in connection with the Registrant's August 2016 Financing.	Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on August 23, 2016.
4.6	Common Share Purchase Warrant Issued to Silicon Valley Bank, dated September 8, 2017.	Incorporated by reference to Exhibit 4.10 to the Quarterly Report on Form 10-Q filed on November 9, 2017.
4.7	Form of Pre-Funded Common Share Purchase Warrant Issued in connection with the Registrants August 2019 Financing.	Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on August 28, 2019
4.8	Form of Series A Common Share Purchase Warrant Issued in connection with the Registrants August 2019 Financing.	Incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed on August 28, 2019
10.1	Form of Securities Purchase Agreement, dated August 26, 2019, by and between the Registrant and the Purchaser.	Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on August 28, 2019.
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

** 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 8th day of November 2019.

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

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: November 8, 2019

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: November 8, 2019

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of Sophiris Bio Inc. (the Company) for the quarter ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Randall E. Woods, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

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

Date: November 8, 2019

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

Exhibit 32.2

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

In connection with the quarterly report on Form 10-Q of Sophiris Bio Inc. (the Company) for the quarter ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Peter T. Slover, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

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

Date: November 8, 2019

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.