
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

May 9, 2019
Date of Report (Date of earliest event reported)

Sophiris Bio Inc.

(Exact name of registrant as specified in its charter)

British Columbia

(State or other jurisdiction
of incorporation)

001-36054

(Commission File Number)

98-1008712

(IRS Employer Identification No.)

**1258 Prospect Street
La Jolla, CA**

(Address of principal executive offices)

92037

(Zip Code)

Registrant's telephone number, including area code: (858) 777-1760

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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.

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

Title of each class
Common Shares, no par value

Trading Symbol(s)
SPHS

Name of each exchange on which registered
The Nasdaq Capital Market

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2019, Sophiris Bio Inc. issued a press release announcing its financial results for the three months ended March 31, 2019. A copy of this press release is furnished herewith as Exhibit 99.1. Pursuant to the rule and regulations of the Securities and Exchange Commission, such exhibit and the information set forth therein and in this Item 2.02 have been furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing regardless of any general incorporation language.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

[99.1 Press release dated May 9, 2019.](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Sophiris Bio Inc.

Dated: May 9, 2019

By: /s/ Peter Slover _____
Peter Slover
Chief Financial Officer



Sophiris Bio Reports First Quarter 2019 Financial Results

SAN DIEGO and VANCOUVER, British Columbia, May 9, 2019 – Sophiris Bio Inc. (NASDAQ: SPHS) (the “Company,” “We” or “Sophiris”), a biopharmaceutical company developing topsalysin (PRX302), a first-in-class, pore-forming protein, in late-stage clinical trials for the treatment of patients with urological diseases, today reported financial results for the first quarter of 2019.

“We continue to have dialog with the European Medicines Agency (EMA) regarding the design for a potential Phase 3 clinical trial, which we developed with input from our scientific advisory board for the treatment of localized prostate cancer,” said Randall E. Woods, president and CEO of Sophiris. “We anticipate obtaining formal scientific advice from the EMA before the end of the second quarter and look forward to taking the next step in the clinical development of topsalysin for the focal treatment of localized prostate cancer before the end of the year. We have cash runway to continue operations into September and believe that the ideal funding option for a potential registration Phase 3 clinical trial will either be a potential development partnership or other strategic transaction.”

Financial Results:

At March 31, 2019, the Company had cash, cash equivalents and securities available-for-sale of \$9.0 million and working capital of \$4.7 million. The Company expects that its cash and cash equivalents and securities available-for-sale will be sufficient to fund its operations through September 2019, assuming no new clinical trials are initiated and the Company continues operating as a going concern. The Company will require significant funding to advance topsalysin in clinical development. As of March 31, 2019, the outstanding principal balance of the Company’s term loan was \$7.0 million. The Company began making principal payments on its term loan in April 2019.

The Company reported a net loss of \$2.4 million or (\$0.08) per share for the three months ended March 31, 2019, compared to net loss of \$3.3 million or (\$0.11) per share for the three months ended March 31, 2018.

Research and development expenses

Research and development expenses were \$1.6 million for the three months ended March 31, 2019, compared to \$3.3 million for the three months ended March 31, 2018. The decrease in research and development costs is primarily attributable to decreases in the costs associated with manufacturing activities for topsalysin, and to a lesser extent, a decrease in clinical costs associated with our Phase 2b clinical trial of topsalysin for localized prostate cancer. Included in the research and development costs for the three months ended March 31, 2019, were costs associated with the completion of 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.

General and administrative expenses

General and administrative expenses were \$1.3 million for the three months ended March 31, 2019, compared to \$1.2 million for the three months ended March 31, 2018.



Gain on revaluation of the warrant liability

Gain on revaluation of the warrant liability was \$0.6 million for the three months ended March 31, 2019, compared to \$1.4 million for the three months ended March 31, 2018. As the Company's warrants may require the Company to pay the warrant holder cash under certain provisions of the warrant, the Company accounts for the warrants as a liability, and the Company is required to calculate the fair value of these warrants each reporting date. Certain inputs utilized in the Company's Black-Scholes fair value calculation may fluctuate in future periods based upon factors which are outside of the Company's control. A significant change in one or more of these inputs used in the calculation of the fair value may cause a significant change to the fair value of the Company's warrant liability, which could also result in a material non-cash gain or loss being reported in the Company's consolidated statement of operations and comprehensive loss.

About Sophiris

Sophiris Bio Inc. is a late-stage clinical biopharmaceutical company developing topsalysin (PRX302) for the treatment of patients with urological diseases. Topsalysin has completed two Phase 2 clinical trials for the focal treatment of localized prostate cancer and is in Phase 3 clinical development for the treatment of the lower urinary tract symptoms of benign prostatic hyperplasia (BPH). Topsalysin is a highly potent ablative agent that is selective and targeted in that it is only activated by enzymatically active PSA which is found in high concentrations in the transition zone of the prostate and in and around prostate tumor cells. For more information, please visit www.sophirisbio.com.

Certain statements included in this press release may be considered forward-looking, including the quotes of Sophiris' President and CEO and expectations about further development of topsalysin (PRX302), plans relating to the design and execution of a Phase 3 clinical trial in localized prostate cancer, Sophiris' liquidity or capital requirements and the ability to obtain additional financing or execute other strategic alternatives. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from those implied by such statements, and therefore these statements should not be read as guarantees of future performance or results. Some of the risks and uncertainties that could cause actual results, performance or achievements to differ include without limitation, risks associated with clinical development, including the uncertainty of the design for any additional clinical trial of topsalysin in localized prostate cancer, risks that the Company will be able to fund future clinical trials or enter into a strategic transaction, risks about the Company's ability to continue as a going concern and other risks and uncertainties identified by Sophiris in its public securities filings with the Securities and Exchange Commission. All forward-looking statements are based on Sophiris' current beliefs as well as assumptions made by and information currently available to Sophiris and relate to, among other things, anticipated financial performance, business prospects, strategies, regulatory developments, clinical trial results, market acceptance, ability to raise capital and future commitments. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Due to risks and uncertainties, including the risks and uncertainties identified by Sophiris in its public securities filings; actual events may differ materially from current expectations. Sophiris disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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

	<u>March 31, 2019</u>	<u>December 31, 2018</u>
Assets:		
Current assets:		
Cash and cash equivalents	\$ 7,678	\$ 10,998
Securities available-for-sale	1,342	1,541
Prepaid expenses and other current assets	<u>424</u>	<u>656</u>
Total current assets	9,444	13,195
Property and equipment, net	3	4
Operating lease right-of-use asset	146	-
Other long-term assets	<u>19</u>	<u>-</u>
Total assets	<u>\$ 9,612</u>	<u>\$ 13,199</u>
Liabilities and shareholders' (deficit) equity:		
Current liabilities:		
Accounts payable	\$ 802	\$ 1,862
Accrued expenses	1,160	1,192
Current portion of promissory note	2,633	1,920
Current portion of operating lease liability	<u>124</u>	<u>-</u>
Total current liabilities	4,719	4,974
Long-term promissory note	4,427	5,091
Warrant liability	846	1,399
Operating lease liability	<u>22</u>	<u>-</u>
Total liabilities	10,014	11,464
Shareholders' (deficit) equity:		
Common shares, unlimited authorized shares, no par value; 30,217,140 and 30,205,915 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	131,247	131,247
Contributed surplus	26,939	26,714
Accumulated other comprehensive gain	98	100
Accumulated deficit	<u>(158,686)</u>	<u>(156,326)</u>
Total shareholders' (deficit) equity	(402)	1,735
Total liabilities and shareholders' (deficit) equity	<u>\$ 9,612</u>	<u>\$ 13,199</u>



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

	Three Months Ended March 31,	
	2019	2018
Operating expenses:		
Research and development	\$ 1,555	\$ 3,330
General and administrative	1,252	1,243
Total operating expenses	2,807	4,573
Other income (expense):		
Interest expense	(167)	(169)
Interest income	61	87
Gain on revaluation of warrant liability	553	1,356
Other expense, net	-	(30)
Total other income	447	1,244
Net loss	\$ (2,360)	\$ (3,329)
Basic and diluted loss per share	\$ (0.08)	\$ (0.11)
Weighted average number of outstanding shares – basic and diluted	30,215	30,111