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 14, 2018
Date of Report (Date of earliest event reported)

Sophiris Bio Inc.
(Exact name of registrant as specified in its charter)

British Columbia	**001-36054**	**98-1008712**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1258 Prospect Street **La Jolla, CA**	**92037**
(Address of principal executive offices)	(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. ☒

Item 2.02 Results of Operations and Financial Condition.

On May 14, 2018, Sophiris Bio Inc. issued a press release announcing its financial results for the three months ended March 31, 2018. 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 14, 2018.

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 14, 2018

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

Sophiris Bio Reports First Quarter 2018 Financial Results and Key Corporate Highlights

SAN DIEGO and VANCOUVER, British Columbia, May 14, 2018 – Sophiris Bio Inc. (NASDAQ: SPHS) (the "Company" or "Sophiris"), a biopharmaceutical company studying topsalysin (PRX302), a first-in-class, pore-forming protein, in late stage clinical trials for the treatment of patients with urological diseases, today reported first quarter 2018 financial results.

"It has been an exciting quarter at Sophiris as we continue to make progress in advancing topsalysin," said Randall E. Woods, president and CEO of Sophiris. "We are looking ahead to two key events in 2018. By the end of the second quarter, we expect to announce the biopsy results from all patients receiving the first administration of topsalysin in our Phase 2b study, and by the end of the year, we expect complete data from all patients including those patients who received a second administration of topsalysin. In advance of these milestones, we have been actively preparing for a Phase 3 registration study, including engaging in initial discussions with European regulatory agencies. In addition, we are actively moving forward with our manufacturing plans to provide sufficient drug substance for a potential Phase 3 registration study in localized prostate cancer and also a potential second Phase 3 in BPH."

Upcoming Milestones:

- **Advancement of Phase 2b Localized Prostate Cancer Study.** The Company announced in December 2017 that it had completed enrollment in its Phase 2b localized prostate cancer study to evaluate the safety and tolerability of topsalysin in treating men with clinically significant localized prostate cancer. A total of 38 patients have been treated with topsalysin in the study. The Company expects biopsy data from all patients receiving the first dose of topsalysin to be available by the end of the second quarter for 2018.

  During the first quarter of 2018, the independent data monitoring committee (IDMC) for the Phase 2b trial met to review the reported adverse events from all patients after the first administration of topsalysin. The IDMC unanimously recommended the clinical trial continue without changes to the protocol. The Company believes that topsalysin continues to demonstrate a favorable safety profile.

  The Phase 2b study was designed to include an option to re-treat patients who did not have any clinically significant adverse events and who responded to the first administration of topsalysin but still had a clinically significant lesion. These patients will have the option to receive a second administration of topsalysin followed by an additional, targeted biopsy six months following the second administration. The Company expects to have final biopsy data in the fourth quarter of 2018 from all patients who receive a second administration. This will be the first data potentially supporting repeat administration of topsalysin.

Financial Results:

At March 31, 2018, the Company had cash, cash equivalents and securities available-for-sale of $22.1 million and working capital of $19.2 million. The Company expects that its cash and cash equivalents will be sufficient to fund its operations to the middle of 2019, assuming no new clinical trials are initiated. The Company reported a net loss of $3.3 million or $(0.11) per share for the three months ended March 31, 2018, compared to a net loss of $2.6 million or $(0.09) per share for the three months ended March 31, 2017.

Research and development expenses

Research and development expenses were $3.3 million for the three months ended March 31, 2018, compared to $1.2 million for the three months ended March 31, 2017. The increase in research and development costs is primarily attributable to increases in the costs associated with manufacturing activities for topsalysin, and to a lesser extent, an increase in clinical costs associated with our Phase 2b clinical trial of topsalysin for the focal treatment of localized prostate cancer.

General and administrative expenses

General and administrative expenses were $1.2 million for the three months ended March 31, 2018, compared to $1.4 million for the three months ended March 31, 2017. The decrease in general and administrative expense is primarily due to a decrease in non-cash stock-based compensation expense which was partially offset by an increase in professional services.

Gain (loss) on revaluation of the warrant liability

Gain on revaluation of the warrant liability was $1.4 million for the three months ended March 31, 2018, compared to a loss of $86,000 for the three months ended March 31, 2017. As these warrants may require the Company to pay the warrant holder cash under certain provisions of the warrant, the Company accounts for these warrants as a liability, and the Company is required to calculate the fair value of these warrants each reporting date. The non-cash gain reported for the three months ended March 31, 2018, is associated with a decrease in the fair value of the Company's warrant liability from December 31, 2017, to March 31, 2018, which is calculated using a Black-Scholes pricing model. 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 is in Phase 2 clinical development for the treatment of localized prostate cancer as well as 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 that is found in high concentrations in the transition zone of the prostate and in and around prostate tumor cells. More than 400 patients have received topsalysin, which continues to appear to be safe and well tolerated. For more information, please visit www.sophirisbio.com.

Certain statements included in this press release may be considered forward-looking, including the quote of Sophiris' President and CEO and expectations about further development of topsalysin (PRX302), including the timing of expected results, plans relating to the design and execution of a Phase 3 clinical trial, plans relating to manufacturing and Sophiris' liquidity or capital requirements. 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 risk that results of the Phase 2b study will not be available when expected and risks that the results of the Phase 2b study will not replicate the results of the completed Phase 2 study of topsalysin for the treatment of localized low to intermediate risk prostate cancer or the study endpoint[s] will not be achieved, risks that the manufacturing of clinical drug supply for Phase 3 clinical trials will not be completed when expected or at the expected costs, risks that the Company will be able to fund future clinical trials and other risks and uncertainties identified by Sophiris in its public securities filings with the SEC. 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)

	March 31, 2018	December 31, 2017
Assets:		
Current assets:		
Cash and cash equivalents	$ 16,286	$ 16,087
Securities available-for-sale	5,767	9,757
Other receivables	13	13
Prepaid expenses	1,009	999
Total current assets	23,075	26,856
Property and equipment, net	3	2
Other long-term assets	19	19
Total assets	$ 23,097	$ 26,877
Liabilities and shareholders' equity:		
Current liabilities:		
Accounts payable	$ 1,132	$ 832
Accrued expenses	1,824	1,499
Current portion of promissory note	958	372
Total current liabilities	3,914	2,703
Long-term promissory note	5,900	6,435
Warrant liability	8,733	10,089
Total liabilities	18,547	19,227
Shareholders' equity:		
Common shares, unlimited authorized shares, no par value; 30,111,153 shares issued and outstanding at March 31, 2018 and December 31, 2017	131,247	131,247
Contributed surplus	26,085	25,854
Accumulated other comprehensive gain	94	97
Accumulated deficit	(152,876)	(149,548)
Total shareholders' equity	4,550	7,650
Total liabilities and shareholders' equity	$ 23,097	$ 26,877

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

	Three Months Ended March 31,	
	2018	**2017**
Operating expenses:		
Research and development	$ 3,330	$ 1,208
General and administrative	1,243	1,369
Total operating expenses	4,573	2,577
Other income (expense):		
Interest expense	(169)	-
Interest income	87	51
Gain (loss) on revaluation of warrant liability	1,356	(86)
Other expense, net	(30)	(7)
Total other income (expense)	1,244	(42)
Net loss	$ (3,329)	$ (2,619)
Basic and diluted loss per share	$ (0.11)	$ (0.09)
Weighted average number of outstanding shares – basic and diluted	30,111	30,111