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

November 13, 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 November 13, 2018, Sophiris Bio Inc. issued a press release announcing its financial results for the three and nine months ended September 30, 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 November 13, 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: November 13, 2018

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

Sophiris Bio Reports Third Quarter 2018 Financial Results and Recent Corporate Highlights

SAN DIEGO and VANCOUVER, British Columbia, November 13, 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 financial results for the third quarter 2018 and recent corporate highlights.

"During the third quarter, we reported top-line six-month biopsy data from two additional patients following a single administration of topsalysin in our ongoing Phase 2b clinical trial in low to intermediate risk localized prostate cancer," said Randall E. Woods, president and CEO of Sophiris. "Both patients were considered partial responders, bringing the total number of patients with a partial response to 15 out of the 37. We continue to believe that the data obtained to date from the single administration of topsalysin supports advancing topsalysin into a single Phase 3 trial for the treatment of localized prostate cancer. We remain on track to report data by the end of next month from patients who received a second administration of topsalysin as part of our Phase 2b trial. Finally, we are preparing for Phase 3 guidance meetings with regulatory agencies. We expect these meetings to take place in the first half of 2019, after which we will provide an update on our Phase 3 trial design."

Third Quarter Corporate Highlights:

- **Updates from Phase 2b trial in localized prostate cancer.** In the third quarter, Sophiris reported top-line six-month follow-up biopsy data from the final two patients enrolled in the trial with pre-identified, clinically-significant localized prostate cancer that were treated with a single administration of topsalysin.

  Based on the six-month follow-up biopsy results, 27% of patients (10/37) demonstrated a clinical response. Of the 10 clinical responders in the Phase 2b trial, six patients experienced a complete ablation with no histological evidence of the targeted tumor remaining. In addition, 41% of patients (15/37) were considered partial responders, meaning that while an effect was seen, some clinically-significant lesion remained as identified by targeted biopsy. 68% of patients (25/37) demonstrated a partial or clinical response to the single administration of topsalysin.

  The Phase 2b study was designed to include an option for qualified patients to receive a second administration of topsalysin six-months after the first administration, provided: (1) the patient did not have any clinically-significant adverse events to either topsalysin or the dosing procedure and (2) some response to the first administration was observed following a targeted biopsy. The objective of re-administering topsalysin is to assess the safety of giving a second administration of topsalysin and to determine if additional clinical benefit is observed six-months after the second administration.

  The Company expects to have six-month follow-up safety and biopsy data from patients who received a second administration of topsalysin in its ongoing Phase 2b trial in localized prostate cancer patients next month.

- **Preparations for Phase 3 trial in localized prostate cancer.** The Company believes that the data generated in the single-administration portion of the Phase 2b prostate cancer study supports the advancement of the program into a single Phase 3 pivotal trial. Currently, the Company is in the process of preparing information for regulatory guidance meetings with the U.S. Food and Drug Administration and the European Medicines Agency which are expected to take place in the first half of 2019, after which the Company will provide an update on the Phase 3 trial design. The Company will evaluate whether future clinical development will include an option to administer a second dose of topsalysin once the Company receives more information from the 10 patients who have received a second dose.

- **Interest only period extended under loan and security agreement.** In September the Company announced that it had met the requirements within its existing loan and security agreement with Silicon Valley Bank to extend the interest only period to March 31, 2019. The Company will begin making interest and principal payments starting on April 1, 2019 and ending on the final payment date of September 1, 2021.

Financial Results:

At September 30, 2018, the Company had cash, cash equivalents and securities available-for-sale of $14.5 million and working capital of $11.7 million. The Company expects that its existing cash and cash equivalents will be sufficient to fund its operations through June 2019, assuming no new clinical trials are initiated. The Company will require significant additional funding to advance topsalysin in clinical development. As of September 30, 2018, the outstanding principal balance of the Company's term loan was $7 million on which the Company is currently making monthly interest only payments.

For the three months ended September 30, 2018

The Company reported a net loss of $2.9 million or ($0.10) per share for the three months ended September 30, 2018, compared to net loss of $2.7 million or ($0.09) per share for the three months ended September 30, 2017.

Research and development expenses

Research and development expenses were $1.8 million for the three months ended September 30, 2018, compared to $1.6 million for the three months ended September 30, 2017. The increase in research and development costs is primarily attributable to increases in the costs associated with manufacturing activities for topsalysin offset in part by a decrease in clinical costs associated with its Phase 2b clinical trial of topsalysin for the treatment of localized prostate cancer.

General and administrative expenses

General and administrative expenses were $1.2 million for the three months ended September 30, 2018, compared to $1.7 million for the three months ended September 30, 2017. The decrease in general and administrative expense is primarily due to decreases in marketing research activities and to a lesser extent a decrease in personnel related expenses.

Gain on revaluation of the warrant liability

Gain on revaluation of the warrant liability was $0.2 million for the three months ended September 30, 2018, compared to a gain of $0.7 million for the three months ended September 30, 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 September 30, 2018, is associated with a decrease in the fair value of the Company's warrant liability from June 30, 2018, to September 30, 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.

For the nine months ended September 30, 2018

The Company reported a net loss of $12.3 million or ($0.41) per share for the nine months ended September 30, 2018 compared to a net loss of $4.7 million or ($0.15) per share for the nine months ended September 30, 2017.

Research and development expenses

Research and development expenses were $8.7 million for the nine months ended September 30, 2018 compared to $4.2 million for the nine months ended September 30, 2017. The increase in research and development costs is primarily attributable to increases in the costs associated with manufacturing activities for topsalysin.

General and administrative expenses

General and administrative expenses were $3.5 million for the nine months ended September 30, 2018 compared to $4.4 million for the nine months ended September 30, 2017. The decrease in general and administrative expense is primarily due to decreases in non-cash stock-based compensation expense and marketing research activities and to lesser extent a decrease in its personnel related costs.

Gain on revaluation of the warrant liability

Gain on revaluation of the warrant liability was $0.1 million for the nine months ended September 30, 2018 as compared to a gain of $3.9 million for the nine months ended September 30, 2017. The non-cash gain reported for the nine months ended September 30, 2018, is associated with a decrease in the fair value of the Company's warrant liability from December 31, 2017, to September 30, 2018.

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 focal 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 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), including the timing of expected results from the Phase 2b trial, 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 final Phase 2b study will not be available when expected and risks that the final safety and/or efficacy data will not support including a second dose option in any future trial risks relating to obtaining regulatory guidance on the endpoints and design of a possible Phase 3 clinical trial, 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)

	September 30, 2018	December 31, 2017
Assets:		
Current assets:		
Cash and cash equivalents	$ 12,048	$ 16,087
Securities available-for-sale	2,498	9,757
Prepaid expenses and other current assets	888	1,012
Total current assets	15,434	26,856
Property and equipment, net	4	2
Other long-term assets	-	19
Total assets	$ 15,438	$ 26,877
Liabilities and shareholders' (deficit) equity:		
Current liabilities:		
Accounts payable	$ 400	$ 832
Accrued expenses	2,098	1,499
Current portion of promissory note	1,212	372
Total current liabilities	3,710	2,703
Long-term promissory note	5,751	6,435
Warrant liability	9,946	10,089
Total liabilities	19,407	19,227
Shareholders' (deficit) equity:		
Common shares, unlimited authorized shares, no par value; 30,111,153 shares issued and outstanding at September 30, 2018 and December 31, 2017	131,247	131,247
Contributed surplus	26,531	25,854
Accumulated other comprehensive gain	99	97
Accumulated deficit	(161,846)	(149,548)
Total shareholders' (deficit) equity	(3,969)	7,650
Total liabilities and shareholders' (deficit) equity	$ 15,438	$ 26,877

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development	$ 1,798	$ 1,649	$ 8,718	$ 4,244
General and administrative	1,155	1,685	3,494	4,422
Total operating expenses	2,953	3,334	12,212	8,666
Other income (expense):				
Interest expense	(173)	(35)	(514)	(35)
Interest income	80	56	258	159
Gain on revaluation of warrant liability	153	670	143	3,905
Other income (expense), net	21	(11)	27	(27)
Total other income (expense)	81	680	(86)	4,002
Net loss	$ (2,872)	$ (2,654)	$ (12,298)	$ (4,664)
Basic and diluted loss per share	$ (0.10)	$ (0.09)	$ (0.41)	$ (0.15)
Weighted average number of outstanding shares – basic and diluted	30,111	30,111	30,111	30,111