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

March 7, 2019
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 March 11, 2019, Sophiris Bio Inc. issued a press release announcing its financial results for the three months and year ended December 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 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On March 7, 2019, the Company received a letter (the "Notice") from the Listing Qualifications Staff of The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that for the last 30 consecutive business days prior to the date of the Notice, 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) (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 has 180 calendar days, or until September 3, 2019, to regain compliance with the Market Value Rule. The Company will regain compliance with the Market Value Rule if the market value of the Company's listed securities closes at or above $35 million for a minimum of 10 consecutive business days anytime during the 180-day compliance period.

The Notice does not have an immediate effect on the listing of the Company's common shares and the Company's common shares will continue to trade on The Nasdaq Capital Market under the symbol "SPHS".

The Company is considering actions that it may take in response to the Notice in order to regain compliance with the Market Value Rule.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated March 13, 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: March 13, 2019

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

Exhibit 99.1

Sophiris Bio Reports Fourth Quarter 2018 and Year-end Financial Results and Recent Corporate Highlights

SAN DIEGO and VANCOUVER, British Columbia, March 13, 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 fourth quarter and full year 2018 and recent corporate highlights.

"During the past year, Sophiris has made important progress in determining the ideal method for topsalysin administration as a focal treatment for localized prostate cancer," said Randall E. Woods, president and CEO of Sophiris. "The Phase 2b study provided a compelling look at this potential, showing that a single administration of topsalysin led to a clinical response in 27% of patients, including a complete ablation of tumor in 16% of patients. Our investigators have also noted that a drug capable of delaying or obviating the need for radical therapy in nearly a third of the patient population with the potential safety profile that we have seen to date could be very attractive for patients with localized intermediate risk prostate cancer."

Allison Hulme, Ph.D., chief operating officer and head of R&D for Sophiris, added: "In recent weeks we have made significant progress on a key next step for the development of topsalysin: the development of a Phase 3 protocol for localized prostate cancer. Based on both the efficacy and the encouraging safety data from our Phase 2 program and the invaluable input from our Scientific Advisory Board who are supportive of our continuing development of topsalysin as a focal therapy, we have finalized a proposed Phase 3 design and initiated the process of obtaining formal scientific advice from the European Medicines Agency (EMA). We are on track to obtain feedback from the EMA in the first half of this year."

Woods added, "In addition to working with regulatory authorities to determine the potential path to market, we have been actively pursuing options to move topsalysin into the final stages of clinical development, and we currently believe that the ideal funding option will either be a potential development partnership or other strategic transaction. We have also re-prioritized some development activities enabling us to extend our cash runway through the third quarter of this year."

Recent Corporate Highlights:

- **Completion of Phase 2b trial in localized prostate cancer.** In December, we provided top-line data from patients who received a second administration of topsalysin in the trial. Eleven of the 37 patients evaluated six months after receiving a single administration of topsalysin went on to receive a second administration. It was determined that both the first and the second administration of topsalysin continue to appear 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. Importantly, a total of 27% of patients (10/37) demonstrated a clinical response six months following the first administration of topsalysin. Six of the ten clinical responders experienced a complete ablation of their tumor with no remaining tumor detected following a targeted biopsy of the treated area.

- **Preparations for Phase 3 trial in localized prostate cancer.** We, along with our Scientific Advisory Board and our other scientific advisors, believe 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, we have initiated formal scientific advice with EMA and in the coming weeks plan to initiate dialog with the US Food and Drug Administration on the single confirmatory Phase 3 design.

- **Completion of topsalysin drug substance manufacturing.** We recently completed the manufacture of a batch of topsalysin drug substance, which is planned for use in the upcoming Phase 3 confirmatory study in localized prostate cancer.

- **Funding of future development of topsalysin.** The management team remains focused on determining the best path forward for funding future clinical development for topsalysin and continues to engage in strategic discussions as part of this effort.

Financial Results:

At December 31, 2018, the Company had cash, cash equivalents and securities available-for-sale of $12.5 million and working capital of $8.2 million. The Company expects that its existing cash and cash equivalents 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 additional funding to advance topsalysin in clinical development. As of December 31, 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 and is scheduled to begin making principal payments in April 2019.

For the three months ended December 31, 2018

The Company reported a net income of $5.5 million or $0.18 per share for the three months ended December 31, 2018, compared to net loss of $4.0 million or ($0.13) per share for the three months ended December 31, 2017. The net income for the three months ended December 31, 2018 was driven by a non-cash gain related to the revaluation of the Company's warrant liability.

Research and development expenses

Research and development expenses were $2.0 million for the three months ended December 31, 2018, compared to $1.9 million for the three months ended December 31, 2017. The increase in research and development costs was primarily attributable to increases in the costs associated with manufacturing activities for topsalysin offset in part by a decrease in personnel related costs.

General and administrative expenses

General and administrative expenses were $0.9 million for the three months ended December 31, 2018, compared to $1.3 million for the three months ended December 31, 2017. The decrease in general and administrative expense was primarily due to decreases in personnel related expenses and marketing research activities.

Gain (loss) on revaluation of the warrant liability

Gain on revaluation of the warrant liability was $8.5 million for the three months ended December 31, 2018, compared to a loss on the revaluation of the warrant liability of $0.6 million for the three months ended December 31, 2017. The Company's outstanding warrants may require it to pay the warrant holder cash under certain provisions of the warrant therefore 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 December 31, 2018, was associated with a decrease in the fair value of the Company's warrant liability from September 30, 2018 to December 31, 2018, which is calculated using a Black-Scholes pricing model. The decrease in the fair market value of the Company's warrant liability was directly related to a decrease in the Company's stock price from September 30, 2018 to December 31, 2018. 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 year ended December 31, 2018

The Company reported a net loss of $6.8 million or ($0.23) per share for the year ended December 31, 2018 compared to a net loss of $8.6 million or ($0.29) per share for the year ended December 31, 2017.

Research and development expenses

Research and development expenses were $10.7 million for the year ended December 31, 2018 compared to $6.2 million for the year ended December 31, 2017. The increase in research and development costs was primarily attributable to increases in the costs associated with manufacturing activities for topsalysin.

General and administrative expenses

General and administrative expenses were $4.4 million for the year ended December 31, 2018 compared to $5.7 million for the year ended December 31, 2017. The decrease in general and administrative expense was primarily due to decreases in non-cash stock-based compensation expense, marketing research activities and its personnel related costs.

Gain on revaluation of the warrant liability

Gain on revaluation of the warrant liability was $8.7 million for the year ended December 31, 2018 as compared to a gain of $3.3 million for the year ended December 31, 2017. The non-cash gain is associated with the change in the fair value of our warrant liability which was calculated using a Black-Scholes pricing model.

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 Phase 2 clinical development 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 the planned Phase 3 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 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)

	December 31, 2018	December 31, 2017
Assets:		
Current assets:		
Cash and cash equivalents	$ 10,998	$ 16,087
Securities available-for-sale	1,541	9,757
Prepaid expenses and other current assets	656	1,012
Total current assets	13,195	26,856
Property and equipment, net	4	2
Other long-term assets	-	19
Total assets	$ 13,199	$ 26,877
Liabilities and shareholders' equity:		
Current liabilities:		
Accounts payable	$ 1,862	$ 832
Accrued expenses	1,192	1,499
Current portion of promissory note	1,920	372
Total current liabilities	4,974	2,703
Long-term promissory note	5,091	6,435
Warrant liability	1,399	10,089
Total liabilities	11,464	19,227
Shareholders' equity:		
Common shares, unlimited authorized shares, no par value; 30,205,915 and 30,111,153 shares issued and outstanding at December 31, 2018 and 2017, respectively	131,247	131,247
Contributed surplus	26,714	25,854
Accumulated other comprehensive gain	100	97
Accumulated deficit	(156,326)	(149,548)
Total shareholders' equity	1,735	7,650
Total liabilities and shareholders' equity	$ 13,199	$ 26,877

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development	$ 1,992	$ 1,942	$ 10,710	$ 6,186
General and administrative	935	1,310	4,429	5,732
Total operating expenses	2,927	3,252	15,139	11,918
Other income (expense):				
Interest expense	(169)	(172)	(684)	(207)
Interest income	75	79	333	238
Gain (loss) on revaluation of warrant liability	8,548	(597)	8,690	3,307
Other income (expense), net	(6)	(21)	22	(48)
Total other income (expense)	8,448	(711)	8,361	3,290
Net income (loss)	$ 5,521	$ (3,963)	$ (6,778)	$ (8,628)
Basic income (loss) per share	$ 0.18	$ (0.13)	$ (0.23)	$ (0.29)
Diluted income (loss) per share	$ 0.18	$ (0.13)	$ (0.23)	$ (0.29)
Weighted average number of outstanding shares – basic	30,125	30,111	30,115	30,111
Weighted average number of outstanding shares –diluted	30,504	30,111	30,115	30,111