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

August 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 August 14, 2018, Sophiris Bio Inc. issued a press release announcing its financial results for the three and six months ended June 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 August 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: August 14, 2018

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

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

SAN DIEGO and VANCOUVER, British Columbia, August 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 financial results for the second quarter 2018 and recent corporate highlights.

"In the second quarter, we announced top-line interim safety and biopsy data following a single administration of topsalysin from our ongoing Phase 2b clinical trial in low to intermediate risk localized prostate cancer," said Randall E. Woods, president and CEO of Sophiris. "The 29% (10/35 patients) clinical response rate we observed was extremely encouraging and provides the foundation for the next stage of development. We and our scientific advisors believe the initial data support advancing topsalysin for the treatment of localized prostate cancer into potential registration trials, and we will continue to evaluate the merits of administering a second dose. Looking ahead for the rest of the year, we are continuing our manufacturing activities to ensure drug supply for potential Phase 3 trials, we plan to advance dialogue with the regulatory agencies around a potential Phase 3 trial design in patients with localized prostate cancer and, once available, we will evaluate safety and biopsy data from the patients who received a second administration of topsalysin."

Second Quarter Corporate Highlights:

- **Positive top-line interim results from Phase 2b trial in localized prostate cancer.** On June 25, the Company announced top-line safety and six month follow-up biopsy data from 35 patients with pre-identified, clinically-significant localized prostate cancer that were treated with a single administration of topsalysin.

  Safety analysis, following a single administration of topsalysin in this study indicates that, to date, topsalysin has been well-tolerated; no hypersensitivity reactions or other serious systemic reactions to study medication have been observed after a single administration.

  Based on the six-month follow-up biopsy results, 29% of patients (10/35) 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, 37% of patients (13/35) experienced a partial response, but the targeted lesion was still deemed clinically-significant based on the targeted biopsy.

  Two additional patients have received six-month follow-up biopsies following their first administration of topsalysin. The Company expects to report updated data following receipt of the results of these biopsies.

- **Independent Data Monitoring Committee recommendation to continue clinical trial as planned.** In May 2018, an Independent Data Monitoring Committee (IDMC) met to review the safety data from all 38 patients administered a single dose of topsalysin as well the safety data available from the first seven patients who received a second administration of topsalysin. At that time, the IDMC unanimously recommended the clinical trial continue without changes to the protocol.

- **Second administration completed in Phase 2b trial.** 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 targeted lesion remaining.

  Eleven patients received a second administration of topsalysin in the Phase 2b clinical trial. The eleventh patient died on the same day he received a second administration of topsalysin. The death did not occur during the procedure. As a precaution, Sophiris elected to halt further re-administration and no additional patients have received a second administration of topsalysin in the Phase 2b clinical trial. The event is under active review.

  The Company expects to have six month follow-up biopsy results and additional safety data from all patients who received a second administration of topsalysin in its ongoing Phase 2b trial in localized prostate cancer patients late in the fourth quarter of 2018.

Financial Results:

At June 30, 2018, the Company had cash, cash equivalents and securities available-for-sale of $18.5 million and working capital of $14.1 million. The Company expects that its 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 June 30, 2018, the outstanding principal balance of our term loan was $7 million on which the Company is currently making monthly interest only payments.

For the three months ended June 30, 2018

The Company reported a net loss of $6.1 million or ($0.20) per share for the three months ended June 30, 2018, compared to net income of $0.6 million or $0.02 per share for the three months ended June 30, 2017. The net income for the three months ended June 30, 2017 was driven by a non-cash gain related to the revaluation of the Company's warrant liability. See an additional discussion below related to this item.

Research and development expenses

Research and development expenses were $3.6 million for the three months ended June 30, 2018, compared to $1.4 million for the three months ended June 30, 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 treatment of localized prostate cancer.

General and administrative expenses

General and administrative expenses were $1.1 million for the three months ended June 30, 2018, compared to $1.4 million for the three months ended June 30, 2017. The decrease in general and administrative expense is primarily due to decreases in non-cash stock-based compensation expense and consulting services.

Gain (loss) on revaluation of the warrant liability

Loss on revaluation of the warrant liability was $1.4 million for the three months ended June 30, 2018, compared to a gain of $3.3 million for the three months ended June 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 loss reported for the three months ended June 30, 2018, is associated with a increase in the fair value of the Company's warrant liability from March 31, 2018, to June 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 six months ended June 30, 2018

The Company reported a net loss of $9.4 million or ($0.31) per share for the six months ended June 30, 2018 compared to a net loss of $2.0 million or ($0.07) per share for the six months ended June 30, 2017.

Research and development expenses

Research and development expenses were $6.9 million for the six months ended June 30, 2018 compared to $2.6 million for the six months ended June 30, 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 treatment of localized prostate cancer.

General and administrative expenses

General and administrative expenses were $2.3 million for the six months ended June 30, 2018 compared to $2.7 million for the six months ended June 30, 2017. The decrease in general and administrative expense is primarily due to decreases in non-cash stock-based compensation expense and consulting services.

Gain (loss) on revaluation of the warrant liability

Loss on revaluation of the warrant liability was $10 thousand for the six months ended June 30, 2018 as compared to a gain of $3.2 million for the six months ended June 30, 2017. The non-cash loss reported for the six months ended June 30, 2018, is associated with an increase in the fair value of our warrant liability from December 31, 2017 to June 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.

Company Contact:
Peter Slover
Chief Financial Officer
(858) 777-1760

Corporate Communications and Media Contact:
Jason Spark
Canale Communications
(619) 849-6005
jason@canalecomm.com

Investor Contact:
Bill Slattery, Jr.
Burns McClellan
(212) 213-0006
bslattery@burnsmc.com

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

	June 30, 2018	December 31, 2017
Assets:		
Current assets:		
Cash and cash equivalents	$ 13,941	$ 16,087
Securities available-for-sale	4,587	9,757
Prepaid expenses and other current assets	1,055	1,012
Total current assets	19,583	26,856
Property and equipment, net	3	2
Other long-term assets	-	19
Total assets	$ 19,586	$ 26,877
Liabilities and shareholders' (deficit) equity:		
Current liabilities:		
Accounts payable	$ 1,271	$ 832
Accrued expenses	2,662	1,499
Current portion of promissory note	1,548	372
Total current liabilities	5,481	2,703
Long-term promissory note	5,362	6,435
Warrant liability	10,099	10,089
Total liabilities	20,942	19,227
Shareholders' (deficit) equity:		
Common shares, unlimited authorized shares, no par value; 30,111,153 shares issued and outstanding at June 30, 2018 and December 31, 2017	131,247	131,247
Contributed surplus	26,274	25,854
Accumulated other comprehensive gain	97	97
Accumulated deficit	(158,974)	(149,548)
Total shareholders' (deficit) equity	(1,356)	7,650
Total liabilities and shareholders' (deficit) equity	$ 19,586	$ 26,877

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 3,591	$ 1,387	$ 6,920	$ 2,595
General and administrative	1,096	1,367	2,340	2,736
Total operating expenses	4,687	2,754	9,260	5,331
Other income (expense):				
Interest expense	(172)	-	(341)	-
Interest income	91	53	178	103
Gain (loss) on revaluation of warrant liability	(1,365)	3,320	(10)	3,234
Other income (expense), net	36	(9)	7	(16)
Total other income (expense)	(1,410)	3,364	(166)	3,321
Net income (loss)	$ (6,097)	$ 610	$ (9,426)	$ (2,010)
Basic income (loss) per share	$ (0.20)	$ 0.02	$ (0.31)	$ (0.07)
Diluted income (loss) per share	$ (0.20)	$ 0.02	$ (0.31)	$ (0.07)
Weighted average number of outstanding shares – basic	30,111	30,111	30,111	30,111
Weighted average number of outstanding shares – diluted	30,111	30,515	30,111	30,111