

SOPHIRIS BIO INC.

FORM 8-K (Current report filing)

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SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

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 15, 2017

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.

Item 2.02 Results of Operations and Financial Condition.

On May 15, 2017, Sophiris Bio Inc. issued a press release announcing its financial results for the three months ended March 31, 2017. 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 15, 2017.

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 15, 2017

By: /s/ Peter Slover

Peter Slover
Chief Financial Officer



Sophiris Bio Reports First Quarter Financial Results and Key Corporate Highlights

SAN DIEGO and VANCOUVER, British Columbia, May 15, 2017 – Sophiris Bio Inc. (NASDAQ: SPHS) (the “Company” or “Sophiris”), a late stage clinical biopharmaceutical company developing topsalsyn (PRX302) for the treatment of patients with urological diseases, today reported first quarter financial results and key corporate highlights.

Key Corporate Highlights:

- o **Update on Phase 2b Localized Prostate Cancer Study** . In March 2017, the Company initiated its Phase 2b open-label localized prostate cancer study with investigational sites in both the UK and US. Five clinical trial sites have been initiated and additional sites are in the process of being initiated.

The Company is currently awaiting final regulatory clearance for the diluent (the medium in which topsalsyn is diluted prior to dosing), which is anticipated this month, at which point the investigational sites will begin dosing patients.

The Company expects to receive the six-month biopsy data for all patients in the first quarter of 2018 assuming enrollment is completed as expected. The Company expects to have complete data on all patients who receive a second dose by the fourth quarter of 2018..

- o **Presented Proof-of-Concept and Phase 2a Data at Global Urological Meetings.** The Company presented positive data from its Phase 2a clinical trial of topsalsyn for the focal treatment of localized prostate cancer at the 112th American Urological Association Annual Meeting and at the 32nd European Association of Urology Congress. Copies of the posters are available on the Company's website at www.sophirisbio.com.

“We now have five clinical trial sites fully trained with additional sites coming onboard,” said Randall E. Woods, president and CEO of Sophiris. “The regulatory approval of the diluent is the last remaining box to check in the administrative work that enables the dosing of patients which we anticipate being able to do in the very near future.”

Financial Results:

At March 31, 2017, the Company had cash, cash equivalents and securities available-for-sale of \$25.7 million and working capital of \$25.6 million. The Company expects that its cash and cash equivalents will be sufficient to fund its operations through the end of 2018. The Company is currently not planning on pursuing a second Phase 3 trial in BPH, unless the Company can secure a development partner to fund a new clinical trial or the Company obtains other financing.

The Company reported a net loss of \$2.6 million (\$0.09 per share) for the three months ended March 31, 2017 compared to a net loss of \$2.2 million (\$0.13 per share) for the three months ended March 31, 2016.

Research and development expenses were \$1.2 million for the three months ended March 31, 2017, compared to \$0.9 million for the three months ended March 31, 2016. The increase in research and development expenses was primarily attributable to an increase in the costs associated with the Company’s on-going Phase 2b clinical trial for the focal treatment of localized prostate cancer which was initiated in March 2017 and, to a lesser extent, an increase in costs associated with manufacturing activities for topsalsyn. These increases were partially offset by a decrease in costs associated with our completed Phase 2a proof of concept clinical trial for low to intermediate risk prostate cancer.



General and administrative expenses were \$1.4 million for the three months ended March 31, 2017 compared to \$1.2 million for the three months ended March 31, 2016. The increase in general and administrative expenses was primarily due to an increase in non-cash stock-based compensation expense which was offset by a reduction in legal and professional services.

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. 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, or 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 the enrollment of the Phase 2b study will not be completed when expected and that results 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, 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:

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

	<u>March 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Assets:		
Current assets:		
Cash and cash equivalents	\$ 8,894	\$ 12,800
Securities available-for-sale	16,800	16,201
Other receivables	86	128
Prepaid expenses	<u>959</u>	<u>846</u>
Total current assets	26,739	29,975
Property and equipment, net	1	4
Other long-term assets	<u>19</u>	<u>19</u>
Total assets	<u>\$ 26,759</u>	<u>\$ 29,998</u>
Liabilities and shareholders' equity:		
Current liabilities:		
Accounts payable	\$ 360	\$ 459
Accrued expenses	<u>765</u>	<u>1,762</u>
Total current liabilities	1,125	2,221
Warrant liability	13,482	13,396
Stock-based compensation liability	<u>23</u>	<u>57</u>
Total liabilities	<u>14,630</u>	<u>15,674</u>
Shareholders' equity:		
Common shares, unlimited authorized shares, no par value; 30,111,153 and 30,107,644 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	131,246	131,245
Contributed surplus	24,336	23,900
Accumulated other comprehensive gain	86	99
Accumulated deficit	<u>(143,539)</u>	<u>(140,920)</u>
Total shareholders' equity	<u>12,129</u>	<u>14,324</u>
Total liabilities and shareholders' equity	<u>\$ 26,759</u>	<u>\$ 29,998</u>



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

	Three Months Ended March	
	31,	
	<u>2017</u>	<u>2016</u>
Operating expenses:		
Research and development	\$ 1,208	\$ 929
General and administrative	1,369	1,164
Total operating expenses	<u>2,577</u>	<u>2,093</u>
Other income (expense):		
Interest expense	-	(150)
Interest income	51	5
Loss on revaluation of warrant liability	(86)	-
Other expense, net	(7)	(4)
Total other expense	<u>(42)</u>	<u>(149)</u>
Net loss	<u>\$ (2,619)</u>	<u>\$ (2,242)</u>
Basic and diluted loss per share	<u>\$ (0.09)</u>	<u>\$ (0.13)</u>
Weighted average number of outstanding shares – basic and diluted	<u>30,111</u>	<u>17,244</u>

Source: Sophiris Bio Inc.