
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 21, 2018

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 March 21, 2018, Sophiris Bio Inc. issued a press release announcing its financial results for the three months and year ended December 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 March 21, 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: March 21, 2018

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



Sophiris Bio Reports Fourth Quarter and Full Year 2017 Financial Results and Key Corporate Highlights

SAN DIEGO and VANCOUVER, British Columbia, March 21, 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 fourth quarter and full year 2017 financial results and key corporate highlights.

Recent Highlights and 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, the purpose of which is 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 of 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 Phase 2b study was designed to include an option to re-treat patients who did not have any clinically significant adverse events and who had a partial response 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 their 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.

- **Presented Proof-of-Concept and Phase 2a Data at Global Urological Meetings.** In 2017, the Company presented positive data from its Phase 2a clinical trial of topsalysin for the 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.
- **Loan and Security Agreement with Silicon Valley Bank.** On September 8, 2017, the Company and Silicon Valley Bank (“SVB”) entered into a Loan and Security Agreement pursuant to which SVB has agreed to lend the Company up to \$10.0 million (subject to certain conditions) in two term loans. On September 12, 2017, the Company borrowed \$7.0 million from SVB under the Loan and Security Agreement.

“Over the past 12 months Sophiris has made important progress advancing topsalysin in clinically significant localized prostate cancer and preparing for a potential Phase 3 registration study,” said Randall E. Woods, president and CEO of Sophiris. “With our Phase 2b study enrolled, we are looking ahead to two key data events this year. The first event is Phase 2b results from the first administration of topsalysin, which are expected to be available by end of the second quarter of 2018. Complete data from patients who were eligible to receive a second administration of topsalysin are expected to be available by the end of the year. The management team has also been diligently preparing for the design and execution of a Phase 3 registration study for the treatment of clinically significant localized prostate cancer in an effort to pave a clear path to commercialization.”

**Financial Results:**

At December 31, 2017, the Company had cash, cash equivalents and securities available-for-sale of \$25.8 million and working capital of \$24.2 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.

For the three months ended December 31, 2017

The Company reported a net loss of \$4.0 million or \$(0.13) per share for the three months ended December 31, 2017, compared to a net loss of \$0.5 million or \$(0.02) per share for the three months ended December 31, 2016.

Research and development expenses

Research and development expenses were \$1.9 million for the three months ended December 31, 2017, compared to \$1.0 million for the three months ended December 31, 2016. The increase in research and development costs is primarily attributable to increases in the costs associated with the Company's Phase 2b clinical trial for the treatment of localized prostate cancer, costs associated with manufacturing activities for topsalysin, and to a lesser extent, an increase in non-cash stock-based compensation expense. These increases are partially offset by a decrease in personnel related costs.

General and administrative expenses

General and administrative expenses were \$1.3 million for the three months ended December 31, 2017, compared to \$1.2 million for the three months ended December 31, 2016. The increase in general and administrative expense is primarily due to increases in market research activities and non-cash stock-based compensation expense. These increases are partially offset by a decrease in personnel related costs.

Gain (loss) on revaluation of the warrant liability

Loss on revaluation of the warrant liability was \$0.6 million for the three months ended December 31, 2017, compared to a gain of \$1.6 million for the three months ended December 31, 2016. Because 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 December 31, 2017, is associated with an increase in the fair value of the Company's warrant liability from September 30, 2017, to December 31, 2017, 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 12 months ended December 31, 2017

The Company reported a net loss of \$8.6 million or \$(0.29) per share for the year ended December 31, 2017, compared to a net loss of \$11.2 million or \$(0.49) per share for the year ended December 31, 2016.

Research and development expenses

Research and development expenses were \$6.2 million for the year ended December 31, 2017, compared to \$3.5 million for the year ended December 31, 2016. The increase in research and development costs is primarily attributable to increases in the costs associated with the Company's Phase 2b for the treatment of localized prostate cancer, costs associated with the manufacturing activities for topsalysin, and to a lesser extent, an increase in the non-cash stock-based compensation expense. These increases are partially offset by decreases in costs associated with the Company's completed Phase 2a proof of concept clinical trial for localized prostate cancer and personnel related costs primarily related to our completed reduction in work force in 2016.

General and administrative expenses

General and administrative expenses were \$5.7 million for the year ended December 31, 2017, compared to \$6.8 million for the year ended December 31, 2016. The decrease in general and administrative expense is primarily due to the inclusion of \$1.6 million in offering costs that were allocated to warrants issued in the Company's public offering completed in 2016. Also contributing to the decrease in general and administrative expense were decreases in costs associated with professional services and personnel related costs. These decreases are partially offset by increases in non-cash stock-based compensation, market research activities and consulting expenses.

Gain (loss) on revaluation of the warrant liability

Gain on revaluation of the warrant liability was \$3.3 million for the year ended December 31, 2017, compared to a loss of \$0.3 million for the year ended December 31, 2016. The non-cash gain reported for the year ended December 31, 2017, is associated with a reduction in the fair value of the Company's warrant liability from December 31, 2016 to December 31, 2017, as 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 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 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 will not be achieved, 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.
Consolidated Balance Sheets
(In thousands, except share amounts)
(Unaudited)

	<u>December 31, 2017</u>	<u>December 31, 2016</u>
Assets:		
Current assets:		
Cash and cash equivalents	\$ 16,087	\$ 12,800
Securities available-for-sale	9,757	16,201
Other receivables	13	128
Prepaid expenses	999	846
Total current assets	26,856	29,975
Property and equipment, net	2	4
Other long-term assets	19	19
Total assets	<u>\$ 26,877</u>	<u>\$ 29,998</u>
Liabilities and shareholders' equity:		
Current liabilities:		
Accounts payable	\$ 832	\$ 459
Accrued expenses	1,499	1,762
Current portion of promissory notes	372	-
Total current liabilities	2,703	2,221
Long-term promissory notes	6,435	-
Warrant liability	10,089	13,396
Stock-based compensation liability	-	57
Total liabilities	<u>19,227</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 December 31, 2017 and 2016, respectively	131,247	131,245
Contributed surplus	25,854	23,900
Accumulated other comprehensive gain	97	99
Accumulated deficit	(149,548)	(140,920)
Total shareholders' equity	<u>7,650</u>	<u>14,324</u>
Total liabilities and shareholders' equity	<u>\$ 26,877</u>	<u>\$ 29,998</u>



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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$ 1,942	\$ 1,007	\$ 6,186	\$ 3,538
General and administrative	1,310	1,204	5,732	6,768
Total operating expenses	3,252	2,211	11,918	10,306
Other income (expense):				
Interest expense	(172)	-	(207)	(373)
Interest income	79	26	238	37
Gain (loss) on revaluation of warrant liability	(597)	1,639	3,307	(330)
Loss on early extinguishment of debt	-	-	-	(180)
Other expense, net	(21)	-	(48)	(12)
Total other income (expense)	(711)	1,665	3,290	(858)
Net loss	\$ (3,963)	\$ (546)	\$ (8,628)	\$ (11,164)
Basic and diluted loss per share	\$ (0.13)	\$ (0.02)	\$ (0.29)	\$ (0.49)
Weighted average number of outstanding shares – basic and diluted	30,111	30,108	30,111	23,002

Source: Sophiris Bio Inc.