SOPHIRIS BIO INC.

FORM 8-K
(Current report filing)

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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

March 27, 2017
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))

Item 2 .0 2 R esults of Operations and Financial Condition.

On March 27, 2017, Sophiris Bio Inc. issued a press release announcing its financial results for the three months and year ended December 31, 2016. 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 27, 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: March 27, 2017

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

Sophiris Bio Reports Fourth Quarter and Full Year 2016 Financial Results and Key Corporate Highlights

SAN DIEGO and VANCOUVER, British Columbia, March 27 , 2017 – Sophiris Bio Inc. (NASDAQ: SPHS) (the "Company" or "Sophiris"), a clinical late-stage biopharmaceutical company developing topsalysin (PRX302) for the treatment of patients with urological diseases, today reported fourth quarter and full year 2016 financial results and key corporate highlights.

Key Corporate Highlights:

- **Advanced Topsalysin (PRX302) in Clinical Development for Localized Prostate Cancer.** During 2016, the Company reported successful results with topsalysin in a completed Phase 2a study for the focal treatment of localized prostate cancer. In 2017, the Company continued the development of topsalysin for the focal treatment of localized prostate cancer with the initiation of a Phase 2b clinical study.

  - **Initiated 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. The primary objective of the study is safety and tolerability of an injection of topsalysin and the key efficacy variable is focal ablation of a clinically significant lesion on biopsy after six months. Approximately 40 patients with localized prostate cancer are expected to be enrolled in the study and patient screening has begun.

    Previously obtained multi-parametric magnetic resonance imaging (mpMRI) of tumor lesions in each patient's prostate, mapped to real-time three dimensional ultrasound will be used in the study to guide an intrasprostatic injection of topsalysin to treat a single, histological-proven, clinically significant lesion area in each patient's prostate.

    Six months following treatment with topsalysin, a targeted biopsy of the treated area will be conducted. The Company expects to receive the six-month biopsy data for all patients in late 2017 or early 2018. Based upon the results of the 6-month biopsy, the study includes an option to potentially re-treat the targeted lesion area with a second dose of topsalysin, with a targeted biopsy to occur six months following the second dose. In order to be eligible for a second dose, the patient cannot have experienced a significant adverse event attributable to topsalysin or the dosing procedure from the first dose and the patient will need to have had a clinical response from the first dose but still have the presence of a clinically significant lesion area. The Company expects to have final biopsy data on all patients who receive a second dose by the third quarter of 2018.

- **Reported Successful Results from a Phase 2a Localized Prostate Cancer Study.** In June 2016, the Company announced successful results from its completed Phase 2a study of topsalysin in the focal treatment of localized prostate cancer. Biopsy data at six months following treatment in 18 patients showed that topsalysin demonstrated the ability to ablate tumor cells in over half of the patients and two patients experienced complete ablation of their targeted tumor with no histological evidence of any tumor remaining at six months.

- **Reported Positive Data at Important Urological Meeting** . The Company presented positive data from its Phase 3 clinical trial of topsalysin as a treatment for the symptoms of benign prostatic hyperplasia ("BPH") as a late breaking poster at the 111th American Urological Association Annual Meeting. A copy of the poster is available on the Company's website at www.sophirisbio.com.

- **Improved Financial Profile to Support Topsalysin Clinical Plans** . During 2016, the Company raised net proceeds of $27.4 million and $7.0 million through two financing transactions. As of December 31, 2016, the Company had cash, cash equivalents and securities available-for-sale of $29.0 million and working capital of $27.8 million. The Company expects that its cash, cash equivalents and securities available-for-sale will allow the Company to operate through the end of 2018.

“During 2016, Sophiris has made significant clinical development progress in advancing topsalysin, a novel and first-in-class targeted biologic,” said Randall E. Woods, president and CEO of Sophiris. “We believe that topsalysin may be an effective treatment to address significant unmet medical needs in two major commercial markets. Topsalysin could potentially provide a new intermediate treatment that may delay or even obviate the need for more radical treatment approaches in both localized prostate cancer as well as BPH. Topsalysin also has the potential to maintain or improve a patient’s quality of life post-treatment while at the same time remaining attractive to payors.”

Financial Results:

At December 31, 2016, the Company had cash, cash equivalents and securities available-for-sale of $29.0 million and working capital of $27.8 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 such new clinical trial or the Company obtains other financing.

For the three months ended December 31, 2016

The Company reported a net loss of $0.5 million ($0.02 per share) for the three months ended December 31, 2016 compared to a net loss of $2.5 million ($0.15 per share) for the three months ended December 31, 2015.

Research and development expenses were $1.0 million for the three months ended December 31, 2016, compared to $1.7 million for the three months ended December 31, 2015. The decrease in research and development expenses were primarily attributable to a decrease in the costs associated with the Company’s Phase 3 PLUS-1 clinical trial which was completed in November 2015 and its Phase 2a proof of concept clinical trial for localized prostate cancer which was completed in June 2016.

General and administrative expenses were $1.2 million for the three months ended December 31, 2016 compared to $0.7 million for the three months ended December 31, 2015. The increase in general and administrative expenses was primarily due to an increase in personnel related costs.

Gain on revaluation of the warrant liability was $1.6 million for the three months ended December 31, 2016. This non-cash gain was associated with the change in the fair value of the Company's warrant liability from September 30, 2016 to December 31, 2016.

For the 12 months ended December 31, 2016

The Company reported a net loss of $11.2 million ($0.49 per share) for the twelve months ended December 31, 2016 compared to a net loss of $14.2 million ($0.84 per share) for the twelve months ended December 31, 2015.

Research and development expenses were $3.5 million for the twelve months ended December 31, 2016 compared to $9.9 million for the twelve months ended December 31, 2015. The decrease in research and development costs were primarily attributable to a decrease of $5.9 million in the costs associated with the Company's completed Phase 3 PLUS-1 clinical trial of topsalysin for the treatment of BPH and to a lesser extent a decrease in costs associated with the Company's Phase 2a proof of concept clinical trial for localized prostate cancer which commenced in May 2015 and was completed in June 2016.

General and administrative expenses were $6.8 million for the twelve months ended December 31, 2016 compared to $3.6 million for the twelve months ended December 31, 2015. The increase is primarily due to the inclusion of $1.6 million in offering costs which were allocated to the warrants issued in connection with the Company's offerings which closed in May and August of 2016. The increase, to a lesser extent, is due to an increase in personnel related costs of $0.8 million and legal, accounting, consulting and professional fees of $0.7 million.

Loss on revaluation of the warrant liability was $0.3 million for the twelve months ended December 31, 2016. The non-cash loss was associated with the change in the fair value of the Company's warrant liability.

Loss on early extinguishment of debt was $0.2 million for the twelve months ended December 31, 2016. This consists of the final payment and a prepayment fee which was offset by the Company's unamortized debt premium resulting from the payoff of its loan with Oxford.

About Sophiris

Sophiris Bio Inc. is a 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 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.

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

	December 31, 2016	December 31, 2015
Assets:		
Current assets:		
Cash and cash equivalents	$ 12,800	$ 5,881
Securities available-for-sale	16,201	2,500
Other receivables	128	8
Prepaid expenses	846	467
Total current assets	29,975	8,856
Property and equipment, net	4	17
Other long-term assets	19	19
Total assets	$ 29,998	$ 8,892
Liabilities and shareholders' equity:		
Current liabilities:		
Accounts payable	$ 459	$ 909
Accrued expenses	1,762	566
Current portion of promissory notes	-	1,771
Total current liabilities	2,221	3,246
Long-term promissory notes	-	3,572
Warrant liability	13,396	-
Stock-based compensation liability	57	168
Total liabilities	15,674	6,986
Shareholders' equity:		
Common shares, unlimited authorized shares, no par value; 30,107,644 and 17,244,736 shares issued and outstanding at December 31, 2016 and 2015, respectively	131,245	113,880
Contributed surplus	23,900	17,683
Accumulated other comprehensive gain	99	99
Accumulated deficit	(140,920)	(129,756)
Total shareholders' equity	14,324	1,906
Total liabilities and shareholders' equity	$ 29,998	$ 8,892

Sophiris Bio Inc.

Consolidated Statement s of Operations and Comprehensive Loss

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended December 3 1 ,		Twelve Months Ended December 3 1 ,	
	2016	**2015**	**2016**	**2015**
Operating expenses:				
Research and development	$ 1,007	$ 1,669	$ 3,538	$ 9,862
General and administrative	1,204	660	6,768	3,626
Total operating expenses	2,211	2,329	10,306	13,488
Other income (expense):				
Interest expense	-	(162)	(373)	(690)
Interest income	26	4	37	22
Gain (loss) on revaluation of warrant liability	1,639	-	(330)	-
Loss on early extinguishment of debt	-	-	(180)	-
Other expense, net	-	(12)	(12)	(41)
Total other income (expense)	1,665	(170)	(858)	(709)
Net loss	$ (546)	$ (2,499)	$ (11,164)	$ (14,197)
Basic and diluted loss per share	$ (0.02)	$ (0.15)	$ (0.49)	$ (0.84)
Weighted average number of outstanding shares – basic and diluted	30,108	16,989	23,002	16,881

Source: Sophiris Bio Inc.