SOPHIRIS BIO INC.
Form 8-K
June 10, 2016

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

June 9, 2016

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 8.01 Other Events.

On June 9, 2016, Sophiris Bio Inc. (the Company) announced the biopsy results from all 18 patients enrolled in the Phase 2a proof-of-concept study of topsalysin for the treatment of localized prostate cancer. The one-time administration of topsalysin was well tolerated with no serious adverse events and no new safety signals being reported. Topsalysin demonstrated an ability to ablate tumor cells in 50 percent of patients (9/18 patients) six months after treatment in a patient population with pre-identified, clinically significant prostate cancer. The Company believes that the results support advancing topsalysin into an additional Phase 2 study to confirm dosing and optimize delivery.

All 18 patients enrolled completed the study. Biopsy data at six months following treatment showed that:

- Two men experienced complete ablation of their targeted tumor with no evidence of any tumor remaining at six months;
- Seven men experienced a partial response, defined as either a reduction in the maximum cancer core length or a reduction in Gleason pattern; and
- Nine patients had no response to treatment.

The Phase 2a proof-of-concept study was a single-center, open-label study at University College London, which is well known for the focal treatment of prostate cancer in the UK. In this study, previously obtained multiparametric magnetic resonance images (mpMRIs) of each patient's prostate tumor lesions were mapped to real-time three-dimensional transrectal ultrasound using an elastic image-fusion software. These images were used to guide the injection of topsalysin to treat a single, histologically-proven, clinically significant prostate cancer lesion. The primary objective of the study was to evaluate the safety and tolerability, and the key efficacy variable was the change in the treated lesion on targeted biopsy after six months. The study was designed to assess whether topsalysin has the potential to provide patients with clinically significant, localized, low to intermediate risk prostate cancer a tissue-sparing cancer treatment that carries little in the way of side effects. A total of 18 patients were enrolled and treated in this study. Detailed results from this study will be presented at a future medical conference.

Certain statements included in this Form 8-K may be considered forward-looking, including expectations about the potential use of topsalysin for the ablation or focal treatment of prostate cancer tumors, expectations that the Company will able to use data from the proof of concept study to develop optimized delivery and dosing protocols for future clinical trials and implications that the Company will be able to continue to advance the clinical development of topsalysin. 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, risk associated with clinical trial development, including the risks that clinical data from a subset of patients may not be predicative of clinical data observed in subsequent patients or in subsequent clinical trials of the same drug candidate and other risks associated with the process of developing, manufacturing commercial scale drug products, obtaining

regulatory approval of and commercializing treatments that are safe and effective, and risks relating to obtaining sufficient capital to enable the Company to continue to operate as a going concern and continue to advance clinical development of topsalysin. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated June 9, 2016.

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: June 10, 2016

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