SOPHIRIS BIO INC.
Form 8-K
February 01, 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

January 28, 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 January 28, 2016, Sophiris Bio Inc. (the Company) announced biopsy data at 6 months for the first seven patients to complete its Phase 2a proof-of-concept study in localized prostate cancer. A review of the biopsy data from the first seven men to complete the study showed that four patients experienced a response to treatment: One patient experienced complete ablation of the tumor where no evidence of the treated tumor remained on a targeted biopsy at 6 months; three patients experienced either a reduction in the maximum cancer core length or a reduction in Gleason pattern; three patients had no response to treatment.

This one-time administration of topsalysin directly into a pre-identified clinically significant tumor appears to be well tolerated with no serious adverse events and no new safety signals being reported. This is consistent with safety observed in the 365 patients that have been treated with topsalysin in the Company's BPH program to date.

The ongoing Phase 2a proof of concept study is 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 are mapped to real-time three-dimensional transrectal ultrasound. These images are used to guide the injection of topsalysin to treat a single, histologically-proven, clinically significant prostate cancer lesion. The primary objective of the study is safety and tolerability, and the key efficacy variable is the change in the treated lesion on targeted biopsy after 6 months. The study is 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. Sophiris expects to have final data on all patients by the end of the second quarter of 2016.

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, statements about the expected timing of completing the ongoing proof of concept study for the treatment of localized low to intermediate risk prostate cancer, expectations that the results of the proof of concept study will be consistent with the results for the first seven patients, expectations that the Company will able to use data from the proof of concept study to develop more effective delivery and dosing protocols or Sophiris' 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, 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 in the endeavor of building a business around such treatments. 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 Form 8-K. 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 January 28, 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: February 1, 2016

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