SOPHIRIS BIO INC.
Form 8-K
June 25, 2018

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 25, 2018

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	**92037**
La Jolla, CA (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))

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 8.01 Other Events.

On June 25, 2018, Sophiris Bio Inc. (the Company) announced top-line interim safety and biopsy data following a single administration of topsalysin from its ongoing open-label, Phase 2b clinical trial. A single administration of topsalysin continues to demonstrate an ability to ablate targeted prostate cancer cells with 10 of 35 patients (29%) demonstrating a clinical response of which 6 patients had a complete ablation with no detectable cancer on targeted biopsy of the treated area. Separately, Sophiris was recently notified that a patient death occurred on the same day as their second administration. The company is currently investigating the cause and as a precaution no additional patients will receive a second administration of topsalysin.

To date, over 450 patients have received a single administration of topsalysin at various doses. The drug continues to appear to be well-tolerated in patients who received a single administration, with no new safety signals reported. In addition, biopsy data from the Phase 2b trial demonstrated that 29% (10/35) of patients sustained a clinical response at six-month follow-up – defined as no detectable tumor following targeted biopsy of the treated lesion or a reduction in the tumor to clinically insignificant.

Top-Line Interim Safety Results from a Single Administration of Topsalysin:

The primary objective of this trial is to evaluate the safety and tolerability of a single, and if applicable, a second administration of topsalysin, when used to focally ablate a histologically-proven, clinically-significant lesion in patients with localized prostate cancer.

To date, a single administration of topsalysin continues to appear safe and well tolerated by patients. No hypersensitivity reactions or other serious systemic reactions to study medication were observed after a single administration. Adverse events considered related to topsalysin and occurring in more than one patient were: dysuria (n=3 patients), urinary retention (n=3 patients), nocturia (n=2 patients), micturition urgency (n=2 patients) and strangury (n=2 patients). All adverse events were considered mild and typically resolved within the same day. One event of micturition urgency was considered severe and resolved the same day and one event of urinary retention was considered moderate and the event was considered resolved after the patient underwent a transuretheral resection of the prostate.

In May 2018, an independent data monitoring committee (IDMC) met to review the safety data from all 38 patients administered a single dose of topsalysin as well the safety data available on the first seven patients who received a second administration of topsalysin. At that time, the IDMC unanimously recommended the clinical trial continue without changes to the protocol.

Top-Line Interim Biopsy Results From a Single Administration of Topsalysin:

A secondary objective of the study is to evaluate the efficacy of a single administration of topsalysin and, if applicable, a second administration of topsalysin to selectively target and focally ablate a pre-identified lesion.

In the Phase 2b clinical trial, 38 patients with pre-identified, clinically-significant low-to-intermediate risk localized prostate cancer received a single administration of topsalysin. Six months after administration, patients received a follow-up targeted biopsy of the treated lesion. At the time of this release, targeted follow-up biopsies have been undertaken and evaluated from 35 of 38 patients treated with a single dose of topsalysin. Two of the remaining patients are expected to receive follow-up biopsies in the coming weeks.

Based on the six-month follow-up biopsy results, 29% of patients (10/35) demonstrated a clinical response, defined in this study as no detectable tumor on targeted biopsy of the treated lesion or a sufficient reduction to deem the lesion clinically-insignificant (cancer lesion of Gleason Score 6 (3+3) and a Maximum Cancer Core Length (MCCL) of less than 6 millimeters). This compares favorably to 17% of patients (3/18) moving to clinically-insignificant disease in the previously completed Phase 2a localized prostate cancer study. Of the 10 clinical responders in the Phase 2b trial, six experienced a complete ablation with no histological evidence of the tumor remaining.

Additionally, the Phase 2b single administration follow-up biopsy data show that:

- 37% of patients (13/35) experienced a partial response, defined as a reduction in MCCL and/or Gleason pattern, but the targeted lesion was still deemed clinically-significant.
- 34% (12/35) of patients did not respond to treatment defined as no change in the targeted lesion or an increase in MCCL and/or Gleason pattern

Administration of a Second Topsalysin Dose:

The Phase 2b prostate cancer study represents the first trial designed to allow qualified patients to receive a second administration of topsalysin six months after initial treatment. To be eligible to receive a second administration, patients could not have experienced a clinically-significant adverse event attributable to either topsalysin or the dosing procedure. Additionally, patients must have demonstrated evidence of a response to treatment with topsalysin, either through a reduction in lesion size, Gleason pattern, or MCCL. The objective of re-administering topsalysin is to determine if additional clinical benefit is observed.

Eleven patients elected to receive a second dose of topsalysin. The patients will continue to be monitored per the trial's protocol and data are expected to be available in the fourth quarter of 2018.

Certain statements included in this press release may be considered forward-looking, including expectations about further development of topsalysin (PRX302), including the timing of expected results, the administration of a second dose, plans relating to the design and execution of a Phase 3 clinical trial, plans relating to manufacturing 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 final Phase 2b study will not be available when expected and risks that the administration of a second does will not be included in

further development, risk that the study endpoint[s] will not be achieved, risks relating to the design of a possible Phase 3 clinical trial, risks that the manufacturing of clinical drug supply for Phase 3 clinical trials will not be completed when expected or at the expected costs, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated June 25, 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: June 25, 2018

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