SOPHIRIS BIO INC.
Form 8-K
December 17, 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

December 17, 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.

Sophiris Bio Inc. (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 provides an update from its Phase 2b study of topsalysin for localized prostate cancer, including top-line safety and biopsy results from the patients who received a second administration of study drug, which appeared to be safe and generally well-tolerated. Additional benefit was not observed on targeted biopsy six months after re-treatment with a second administration of topsalysin.

As previously stated, a total of 27% of patients (10/37) demonstrated a clinical response six months following a single administration of topsalysin. Six of the ten clinical responders experienced a complete ablation of their tumor. Based on these results, the Company is moving forward with its plans to propose a single Phase 3 registration trial design using a single administration of topsalysin, which it will discuss with regulatory agencies in the coming months.

Final Safety and Biopsy Results from a Single Administration of Topsalysin:

The primary objectives of the Phase 2b clinical study were to evaluate the safety, tolerability and efficacy, as assessed by targeted biopsy, of a single administration of topsalysin, when used to focally ablate a histologically-proven, clinically-significant lesion in patients with low-to-intermediate localized prostate cancer. In the trial, 38 patients received a single administration of topsalysin. Six months after administration, 37 of the 38 patients received a follow-up targeted biopsy of the treated lesion, with one patient having been lost to follow-up following re-location.

Based on the final results of the study, a single administration of topsalysin continues to appear safe and well-tolerated by patients. Adverse events considered related to topsalysin were typically mild and typically occurred and were resolved on the day of the administration. In addition, urine function was preserved, no sexual dysfunction, no hypersensitivity reactions or other serious systemic reactions to study medication were observed after a single administration.

The final six-month follow-up biopsy results demonstrated that 27% of patients (10/37) achieved 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 (Gleason Score 6 (3+3) and a Maximum Cancer Core Length (MCCL) of less than 6 millimeters). Of the ten clinical responders in the Phase 2b study, six men experienced a complete ablation with no histological evidence of the tumor remaining.

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

41% of patients (15/37) experienced a partial response, defined as a reduction in MCCL and/or Gleason pattern, but the targeted lesion was still deemed clinically-significant; and
32% (12/37) of patients did not respond to treatment, defined as no change in the targeted lesion or an increase in MCCL and/or Gleason pattern.

Top-line Results from the Second Administration of Topsalysin

Another important objective for this Phase 2b study was to evaluate the safety of re-administering topsalysin, and to determine if additional clinical benefit could be observed following re-treatment of the targeted lesion six months after initial treatment, as assessed by targeted biopsy six months after re-administration. To be eligible to receive a second dose, patients must 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 the first treatment with topsalysin, either through a reduction in lesion size, Gleason pattern, or MCCL. No patients who had a complete ablation following the first dose received a second administration.

A top-line review of the safety data from a total of ten patients who received a second administration indicates that a second dose appears to be both safe and well-tolerated by patients. There were no adverse events considered related to topsalysin that were experienced by more than one patient following the second administration. The adverse events that were considered related to topsalysin were typically mild and resolved within two days. Importantly, no hypersensitivity reaction or other serious systemic reactions to topsalysin were observed. Urine function was preserved and there were no reports of sexual dysfunction related to topsalysin. As previously reported, an eleventh patient received a second dose but unfortunately experienced a serious adverse event of sudden cardiac death which, following a thorough review of medical records, serology results and autopsy findings, was considered unlikely related to topsalysin by both the investigator and Company.

Based on the top-line review of the six-month biopsy results following the second administration of topsalysin, the Company has concluded that there appears to be no additional clinical benefit gained with a second administration. The decision to include a second administration of topsalysin in any future clinical studies is under review by the Company.

Certain statements included in this press release may be considered forward-looking, including expectations about further development of topsalysin (PRX302), including the expected advancement of topsalysin to a single Phase 3 clinical trial for the treatment of localized prostate cancer and the expectations that the company will be able to fund a Phase 3 clinical trial. 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 risks relating to the design of a possible Phase 3 clinical trial in localized prostate cancer, 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 risks relating to the timing and conduct of any future Phase 3 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 December 17, 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: December 17, 2018

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