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

August 29, 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 **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))

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") announced the conclusion of the ongoing investigation into the previously reported death of a patient in the company's Phase 2b trial for the treatment of localized prostate cancer is unlikely to be related to either topsalysin or the procedure. The regulatory authorities in the United States and the United Kingdom where the study is being conducted have been notified.

Following a comprehensive review of the recently received autopsy report, together with hospital records and the negative serology results for acute hypersensitivity, the Investigator and Company believe that the cause of death is consistent with the autopsy finding of Sudden Cardiac Death (SCD) probably due to an arrhythmia. The autopsy found that the patient had multiple risk factors for SCD. The Investigator and the Company concur that the event is unlikely related to topsalysin or the procedure.

Certain statements included in this press release may be considered forward-looking. 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. 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, market acceptance 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 August 29, 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: August 30, 2018

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

Sophiris Bio Updates on Phase 2b Localized Prostate Cancer Trial

Previously reported patient death determined unlikely to be related to topsalysin

SAN DIEGO and VANCOUVER, British Columbia, August 29, 2018 – Sophiris Bio Inc. (NASDAQ: SPHS) (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 announced the conclusion of the ongoing investigation into the previously reported death of a patient in the Company's Phase 2b trial for the treatment of localized prostate cancer is unlikely to be related to either topsalysin or the procedure. The regulatory authorities in the United States and the United Kingdom where the study is being conducted have been notified.

Following a comprehensive review of the recently received autopsy report, together with hospital records and the negative serology results for acute hypersensitivity, the Investigator and Company believe that the cause of death is consistent with the autopsy finding of Sudden Cardiac Death (SCD) probably due to an arrhythmia. The autopsy found that the patient had multiple risk factors for SCD. The investigator and the Company concur that the event is unlikely related to topsalysin or the procedure.

"As we have previously reported, over 450 patients have received topsalysin at various doses. Topsalysin continues to appear to be well-tolerated with no new safety signals reported," said Randall E. Woods, President and Chief Executive Officer of Sophiris. "We are very encouraged with the results from the single administration of topsalysin in our Phase 2b study that were reported in June 2018. We continue to plan and move forward with a potential Phase 3 study design based on the response rates and safety profile we have observed to date. We look forward to reporting the complete efficacy and safety data from the Phase 2b study by the end of the year which will include the biopsy and safety data from the 10 patients who received a second administration of topsalysin."

About Localized Prostate Cancer

Prostate cancer is the second most common form of cancer in men in the US with an estimated 161,000 new cases in 2017. Approximately 80 percent of patients in the US are diagnosed with localized disease. Research has shown that patients with early, localized disease have a low likelihood of the cancer spreading beyond the confines of the prostate; however, many men with clinically significant localized disease choose to undergo radical treatment. Radical therapies include surgery to remove the entire prostate and/or radiation. Potential toxicities from radical treatments can be significant and permanent and include erectile dysfunction, urinary incontinence, and rectal toxicity.

About Topsalysin

Topsalysin (PRX302), an innovative, "First-in-Class" transmembrane pore-forming protein, was genetically modified to be activated only by enzymatically-active PSA, which is produced in large quantities within the prostate of men with prostate cancer. The targeted focal treatment of prostate cancer is in line with current treatment trends for solid tumors such as breast and liver, where the goal is to remove the tumor and preserve as much of the organ and organ function as possible.

Topsalysin has the potential to provide a targeted focal therapy for the ablation of localized prostate cancer lesions while potentially avoiding many of the complications and side effects associated with whole gland radical treatments. The increasing use of multiparametric magnetic resonance imaging (mpMRI) and advances in software to co-register previously obtained mpMRI images with real-time three-dimensional ultrasound images enables urologists to more accurately locate tumors within the prostate when taking biopsies. This increases the accuracy with which men with clinically significant lesions are identified. It also enables the injection of an ablative agent, such as topsalysin, directly into previously identified clinically significant tumors located within the prostate.

About Sophiris

Sophiris Bio Inc. is a late-stage clinical 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 the 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 450 patients have received treatment with 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 quotes of Sophiris' President and CEO and expectations about further development of topsalysin (PRX302), including the timing of expected results, the expected safety or efficacy results for the full study, the administration of a second dose and plans relating to the design and execution of 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 that results of the final Phase 2b study will not be available when expected, risks that the administration of a second dose 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.

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