

SOPHIRIS BIO INC.
Form 8-K
August 30, 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

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 (Commission File Number) (IRS Employer Identification No.)
of incorporation)

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*