SOPHIRIS BIO INC.
Form 8-K
November 12, 2015

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

November 10, 2015

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 November 10, 2015, Sophiris Bio Inc. (the Company) announced final results from its Phase 3 "PLUS-1" study of PRX302 as a treatment for lower urinary tract symptoms of benign prostatic hyperplasia (BPH, enlarged prostate). PRX302 demonstrated a statistically significant improvement in International Prostate Symptom Score (IPSS) total score from baseline over 12 months compared to the vehicle-only control group (7.60 vs. 6.58 point overall improvement; p = 0.043), the primary endpoint of the study. PRX302 continues to demonstrate a favorable safety profile, with no evidence of any treatment related sexual or cardiovascular side effects.

Efficacy Analysis

The primary efficacy endpoint of the IPSS total score change from baseline over 52 weeks was analyzed, per guidance from the FDA, using the repeated measures linear mixed model applied to the modified intent-to-treat population of every patient randomized and dosed with study drug. The 7.60-point overall improvement for the PRX302 group was statistically significantly superior to the 6.58 point improvement in the vehicle-only group (p = 0.043).

In a secondary efficacy analysis of IPSS total score using an ANCOVA model and LOCF (Last Observation Carried Forward) to impute missing post-baseline data, the improvement in IPSS for PRX302 was well sustained over the 52 weeks following the single administration. The maximal effect of 8.31 points improvement in IPSS vs vehicle 6.89 points (p = 0.012) was achieved at Week 18 with 8.04 points of improvement for PRX302 still remaining at Week 52 vs 6.64 points for patients treated with vehicle only (p = 0.022) representing an end-of-study preservation of 97% of the peak benefit.

Secondary efficacy endpoints included analysis of Qmax (maximum urine flow) change from baseline over 52 weeks by the repeated measures linear mixed model, which showed overall improvement of 1.77 mL/sec for PRX302, representing a statistical trend that narrowly missed statistical significance (p = 0.055) compared to the vehicle group.

An additional efficacy endpoint was the patient self-assessment of disease specific Quality of Life. On the 0 to 6 point Quality of Life (QOL) from the IPSS questionnaire, the PRX302 average change from the 4.5 point baseline was a sustained 1.6 to 1.7 points improvement from Weeks 18 through 52, which was statistically significantly superior to vehicle for every post-baseline visit beginning at Week 18 (reaching p = 0.004).

Safety Analysis

PRX302 treatment was generally well-tolerated, and no patient was withdrawn from the study or had their study drug injection altered because of an adverse event (AE). The safety profile was consistent with that reported in the TRIUMPH Phase 2 trial published in the Journal of Urology in April 2013. Adverse events occurring in ≥5% of

patients treated with PRX302 regardless of assessed relatedness to study treatment are set forth in the table below. These adverse events are not unexpected manifestations of the intraprostatic cellular destruction and resultant inflammation integral to the PRX302 mechanism of action. The median duration for each of these adverse events was typically less than one day. In general, these adverse events were mild or moderate, transient, began within the first few days after treatment (primarily on the same day as the study drug injection) and were resolved without consequences.

Adverse Events Occurring in ≥5% of Patients Treated with PRX302 (Safety Population)

Reported Any Time over the Entire 52 Weeks of Study and Regardless of Assessed Relatedness to Study Treatment:

Adverse Event[1]	**Vehicle (N=240) n (%)**		**PRX302 (N=239) n (%)**	
Dysuria (e.g., burning, pain, or discomfort on urination)	20	(8.3)	48	(20.1)
Haematuria (microscopic or visible red blood cells in urine)	36	(15.0)	45	(18.8)
Pollakiuria (frequent urination)	14	(5.8)	23	(9.6)
Pyrexia (fever)	10	(4.2)	21	(8.8)
Perineal Pain	13	(5.4)	21	(8.8)

[1](MedDRA Dictionary Preferred Terms)

The incidence of serious AEs (SAEs) was similar in both treatment groups. There were two SAEs assessed by the Investigator as at least possibly related to treatment for PRX302 and one such SAE for vehicle. The PRX302-related SAEs were moderate events of “acute non-infectious prostatitis” and “fever following prostate procedure” not unexpected manifestations of the intraprostatic cellular destruction and resultant inflammation integral to the PRX302 mechanism of action. The vehicle-related SAE was a mild event of “urinary tract infection.”

PLUS-1 Study Background

The Phase 3 “PLUS-1” study is an international, multicenter, randomized, double-blind, and vehicle-controlled trial to assess the efficacy and safety of a single intraprostatic administration of PRX302 (0.6 µg/g prostate) for the treatment of BPH. Patients were randomized in a 1:1 ratio to either PRX302 or vehicle-only injection, and then monitored for 1 year. A total of 479 patients with moderate to severe BPH were enrolled and dosed by September 2014. The 52-week completion rate was 91.9%, with a similar number of premature withdrawals from study for the PRX302 group (8.8%) vs. the vehicle group (7.5%). On average, the injection itself was completed in less than 4 minutes.

Treatment groups were well balanced at baseline, including average IPSS total score (21.2 points both groups), Qmax (maximum urine flow) (9.5 mL/sec both groups), total prostate volume (49.8 mL for PRX302 vs. 48.1 mL vehicle), prior BPH treatment (55.2% PRX302 vs. 55.1% vehicle), and quality of life (4.5 points both groups, “mostly dissatisfied” to “unhappy” with current urinary condition).

Certain statements included in this Form 8-K may be considered forward-looking including any implied statements about future development of PRX302 for the treatment of symptoms of BPH or the outcome of the proof of concept trial of PRX302 for the treatment of localized prostate cancer. 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 the Company's current beliefs as well as assumptions made by and information currently available to Company. 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 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 risks relating to raising sufficient capital to fund development and commercialization of drug products risks relating to the Company's ability to raise capital to fund an additional Phase 3 clinical trial and the risks and uncertainties identified by Company in its public securities filings; actual events may differ materially from current expectations. The Company 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 November 10, 2015.

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: November 10, 2015

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