SOPHIRIS BIO INC.
Form 424B3
January 26, 2015
**Filed Pursuant to Rule 424(b)(3)**
**Registration No. 333-196331**

**Prospectus Supplement No. 4**

(to prospectus dated June 23, 2014)

**Sophiris Bio Inc.**

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This Prospectus Supplement No. 4 supplements and amends the prospectus dated June 23, 2014, or the Original Prospectus, and Prospectus Supplement No. 2 thereto, dated July 7, 2014, Prospectus Supplement No. 3 thereto, dated August 7, 2014 and Prospectus Supplement No. 4 there, dated January 26, 2015, which we refer collectively to as the Prospectus, relating to the sale of an aggregate of 3,409,629 of our common shares, no par value, by the selling shareholder identified in the Original Prospectus.

On December 15, 2014, we filed with the Securities and Exchange Commission a Current Report on Form 8-K relating to the findings from an administrative interim analysis of efficacy in our ongoing Phase 3 trial of PRX302 as a treatment for lower urinary tract symptoms of BPH. The information set forth below supplements and amends the information contained in the Prospectus. This Prospectus Supplement No. 4 should be read in conjunction with, and delivered with, the Prospectus and is qualified by reference to the Prospectus except to the extent that the information in this Prospectus Supplement No. 4 supersedes the information contained in the Prospectus.

The prices at which the selling shareholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the selling shareholder. However, we may receive proceeds of up to $15.0 million from the sale of our common shares to the selling shareholder, pursuant to a common stock purchase agreement entered into with the selling shareholder on May 16, 2014, including proceeds that we have already received thereunder.

The selling shareholder is an “underwriter” within the meaning of the Securities Act of 1933, as amended. We will pay the expenses of registering these shares, but all selling and other expenses incurred by the selling shareholder will be paid by the selling shareholder.

Our common shares trade on the NASDAQ Global Market, or NASDAQ, under the ticker symbol “SPHS”. On January 23, 2015, the last reported sale price per common share was $0.46 per share.

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**This investment involves risks. See “Risk Factors” on page 7 of the Original Prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

**The date of this Prospectus Supplement No. 4 is January 26, 2015.**

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**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 15, 2014**

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 December 15, 2014, Sophiris Bio Inc. (the Company) announced findings from an administrative interim analysis of efficacy in its ongoing Phase 3 "PLUS-1" trial of PRX302 as a treatment for lower urinary tract symptoms of BPH. The Independent Data Monitoring Committee (IDMC) reported that a predefined efficacy threshold following treatment was not achieved. This administrative interim analysis was conducted specifically for planning subsequent clinical trials. The ongoing "PLUS-1" study is unaffected by this recommendation, and all patients in the study will continue to be followed to enable the evaluation of the primary efficacy endpoint at 52 weeks.

The IDMC completed the planned, protocol-specified administrative analysis of efficacy based on the International Prostate Symptom Score (IPSS) change from baseline to Week 12 for all 479 patients dosed in the study. The protocol-specified administrative analysis of efficacy threshold at 12 weeks is defined as an IPSS treatment effect of ≥ 2.0 points favoring PRX302 over vehicle-only (i.e.average IPSS total score change from baseline (CFB) for PRX302 minus IPSS CFB for vehicle-only). Simultaneously with this administrative interim efficacy analysis, the IDMC completed its fifth and final periodic analysis of unblinded safety data and reported no safety concerns to Sophiris. There were no events of sepsis reported post administration of study drug in this trial.

The IDMC conveyed this recommendation to Sophiris in a manner that would not unblind the study nor reveal the actual measured treatment effect. Sophiris and others directly involved in the study will remain blinded to treatment group assignment as the 52 week monitoring period continues until after the last patient has completed the study, which is anticipated to be in September 2015

The Phase 3 "PLUS-1" study is an international, multicenter, randomized, double-blind, and vehicle-controlled trial to assess the safety and efficacy of a single intraprostatic administration of PRX302 (0.6 μg/g prostate) for the treatment of BPH. Enrollment and dosing in the study were completed in September 2014. The primary endpoint is the IPSS total score change from baseline over 52 weeks. Secondary endpoints include Qmax (maximum urine flow) change from baseline over 52 weeks. The full sample size of 220 patients per group would provide 90% power to detect a ≥ 2.5 point treatment group difference in IPSS total score change from baseline using a 2 sided test at Type 1 error 0.05, assuming a standard deviation of ≤ 8.

*Certain statements included in this Form 8-K may be considered forward-looking including any implied statements about the results of the ongoing clinical trial of PRX302 or the efficacy of PRX302. 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 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 that the interim analysis after three months from treatment may not be indicative of the final results after 12 months from treatment, 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 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 15, 2014.

**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 15, 2014

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

**Exhibit 99.1**

**Sophiris Bio Reports Administrative Interim Analysis for the "PLUS-1" Phase 3 Trial of PRX302 for Benign Prostatic Hyperplasia**

**San Diego and Vancouver, British Columbia, December 15, 2014** – Sophiris Bio Inc. (NASDAQ: SPHS) (the "Company" or "Sophiris"), a biopharmaceutical company developing PRX302 (topsalysin) for the treatment of symptoms of benign prostatic hyperplasia (BPH, enlarged prostate) and the treatment of localized prostate cancer, today announced findings from an administrative interim analysis of efficacy in its ongoing Phase 3 "PLUS-1" trial of PRX302 as a treatment for lower urinary tract symptoms of BPH. The Independent Data Monitoring Committee (IDMC) reported that a predefined efficacy threshold following treatment was not achieved. This administrative interim analysis was conducted specifically for planning subsequent clinical trials. The ongoing "PLUS-1" study is unaffected by this recommendation, and all patients in the study will continue to be followed to enable the evaluation of the primary efficacy endpoint at 52 weeks.

"Patients will continue to be followed for the duration of the study to evaluate the International Prostate Symptom Score (IPSS) total score change from baseline over 52 weeks – the primary endpoint of the study," stated Randall Woods, president and CEO of Sophiris. "We expect to be able to provide further commentary on the activity of PRX302 once the study is complete and all the data through 52 weeks are unblinded and analyzed in the fourth quarter of 2015."

The IDMC completed the planned, protocol-specified administrative analysis of efficacy based on the IPSS change from baseline to Week 12 for all 479 patients dosed in the study. Simultaneously with this administrative interim efficacy analysis, the IDMC completed its fifth and final periodic analysis of unblinded safety data and reported no safety concerns to Sophiris. There were no events of sepsis reported post administration of study drug in this trial.

The IDMC conveyed this recommendation to Sophiris in a manner that would not unblind the study nor reveal the actual measured treatment effect. Sophiris and others directly involved in the study will remain blinded to treatment group assignment as the 52 week monitoring period continues until after the last patient has completed the study, which is anticipated to be in September 2015

The Phase 3 "PLUS-1" study is an international, multicenter, randomized, double-blind, and vehicle-controlled trial to assess the safety and efficacy of a single intraprostatic administration of PRX302 (0.6 µg/g prostate) for the treatment of BPH. Enrollment and dosing in the study were completed in September 2014. The primary endpoint is the IPSS

total score change from baseline over 52 weeks. Secondary endpoints include Qmax (maximum urine flow) change from baseline over 52 weeks.

**About Sophiris**

Sophiris Bio Inc. is a biopharmaceutical company developing PRX302, a clinical-stage, targeted therapy for the treatment of the symptoms of BPH and treatment of low to intermediate risk localized prostate cancer. PRX302 is in Phase 3 clinical development for the treatment of the symptoms of BPH and is designed to be as efficacious as pharmaceuticals, less invasive than the surgical interventions, and without the sexual side effects seen with existing treatments. Sophiris plans to initiate a Phase 2 proof of concept study of PRX302 for the treatment of localized low to intermediate risk prostate cancer prior to the end of the first quarter of 2015. For more information, please visit www.sophiris.com.

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**Company Contact:**

Peter Slover

Chief Financial Officer

(858) 777-1760

**Corporate Communications and Investor Relations:**

Michael Moore
Equicom Group
Investor Relations
858-886-7813
mmoore@tmxequicom.com

Jason I. Spark
Canale Communications, Inc.
Corporate Communications and IR
619-849-6005
jason@canalecomm.com