SOPHIRIS BIO INC.
Form 424B3
November 12, 2015
Filed Pursuant to Rule 424(b)(3)
Registration No. 333-196331

Prospectus Supplement No. 9

(to prospectus dated May 6, 2015)

Sophiris Bio Inc.

This Prospectus Supplement No. 9 supplements and amends the prospectus dated May 6, 2015, or the Original Prospectus, and Prospectus Supplement No. 1 thereto, dated May 15, 2015, Prospectus Supplement No. 2 thereto, dated May 29, 2015, Prospectus Supplement No. 3 thereto, dated August 24, 2015, Prospectus Supplement No. 4 thereto, dated August 24, 2015, Prospectus Supplement No. 5 thereto, dated August 24, 2015, Prospectus No. 6 thereto, dated August 24, 2015 and Prospectus No. 7 thereto, dated October 29, 2015, and No. 8 thereto, dated October 29, 2015 which we refer to 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 November 10, 2015, Sophiris Bio Inc. announced final positive 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). The information set forth below supplements and amends the information contained in the Prospectus. This Prospectus Supplement No. 9 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. 9 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 Capital Market, or NASDAQ, under the ticker symbol "SPHS". On November 11, 2015, the last reported sale price per common share was $3.20 per share.

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. 9 is 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

Exhibit 99.1

Sophiris Bio Phase 3 BPH Study Successfully Meets Primary Endpoint

A single treatment with PRX302 (topsalysin) demonstrated a statistically significant improvement in BPH symptoms over a 12 month period

SAN DIEGO and VANCOUVER, British Columbia – November 10, 2015 – Sophiris Bio Inc. (NASDAQ: SPHS) (the "Company" or "Sophiris"), a biopharmaceutical company developing PRX302 (topsalysin) for the treatment of urological diseases, today 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.

"A 7.60 point improvement in IPSS total score over 12 months indicates that patients are experiencing a significant relief of their BPH symptoms and improvement in their quality of life following a single treatment with PRX302," said Dr. Allison Hulme, chief operating officer and head of research and development at Sophiris Bio. "Oral medications such as alpha blockers and 5-alpha reductase inhibitors typically demonstrate a 3-6 point improvement in IPSS total score. We believe that a statistically significant improvement in IPSS, if replicated in a second Phase 3 trial, may be sufficient for registration with the FDA."

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.

”The combination of the efficacy and safety profile makes PRX302 a particularly compelling potential option for men suffering from BPH and may help men avoid more invasive, surgical procedures,” said Randall Woods, President and CEO of Sophiris. “PRX302 is the only single-administration investigational treatment for BPH that has demonstrated a statistically significant improvement in symptoms of BPH, is well-tolerated, and has a favorable safety profile. The results of the study demonstrate clear biological activity of PRX302 and increase our confidence in the mechanism of action.”

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.

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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).

About PRX302

PRX302 (topsalysin) is a modified recombinant protein that has been engineered to be selectively activated by an enzyme in the prostate, leading to localized cell death and tissue disruption without damaging neighboring tissue and nerves. PRX302 binds to the GPI-anchored receptors on the cell surface of prostate cells. Once activated by PSA, PRX302 combines with other activated PRX302 molecules, forming stable transmembrane pores that induce cell death. The prostate specific activation of PRX302 by enzymatically active PSA thus limits exposure of non-prostate tissues to the drug’s activity, contributing to the safety of the therapy.

About BPH Market Opportunity

Our market research suggests that as many as 36 million men in the United States are affected by BPH with approximately 5 million of these men suffering from bothersome symptoms. While 3 million men are prescribed pharmaceuticals for BPH in the US each year, these treatments lack sustainable efficacy and are associated with undesirable side effects including sexual dysfunction. With current pharmaceutical treatments, symptoms will usually return if medication is discontinued. More aggressive treatment options include invasive surgical procedures that may be successful at treating BPH. However, any type of prostate surgery can cause side effects, such as semen flowing backward into the bladder (retrograde ejaculation), loss of bladder control (incontinence) and impotence (erectile dysfunction). There is a demand for better balance between efficacy, safety and quality of life.

About Sophiris

Sophiris Bio Inc. is a biopharmaceutical company developing PRX302, a clinical-stage, targeted therapy for the treatment of urological diseases. 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. PRX302 is also currently in a Phase 2a proof of concept study for the treatment of localized low to intermediate risk prostate cancer. For more information, please visit www.sophiris.com.

Certain statements included in this press release may be considered forward-looking, including the quotes of Sophiris’ President and CEO and our COO and head of research and development and any expectations relating to

future development of PRX302 for the treatment of symptoms of BPH, including a second Phase 3 clinical trial necessary to pursue registration of PRX302, the results of the Phase 2a proof of concept trial for the treatment of localized low to intermediate risk prostate cancer l or Sophiris' capital requirements. 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 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. 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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Source: Sophiris Bio Inc.