SOPHIRIS BIO INC.
Form 424B3
February 01, 2016
Filed Pursuant to Rule 424(b)(3)
Registration No. 333-196331

Prospectus Supplement No. 12

(to prospectus dated May 6, 2015)

Sophiris Bio Inc.

This Prospectus Supplement No. 12 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, No. 8 thereto, dated October 29, 2015, No. 9 thereto, dated November 12, 2015, No. 10 thereto, dated November 18, 2015 and No. 11 thereto, dated November 30, 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 January 28, 2016, we filed with the Securities and Exchange Commission a Current Report on Form 8-K related to our announcement of preliminary data from our Phase 2a proof of concept study in localized prostate cancer. The information set forth below supplements and amends the information contained in the Prospectus. This Prospectus Supplement No. 12 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. 12 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 January 29, 2016, the last reported sale price per common share was $1.93 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. 12 is February 1, 2016

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

January 28, 2016

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 January 28, 2016, Sophiris Bio Inc. (the Company) announced biopsy data at 6 months for the first seven patients to complete its Phase 2a proof-of-concept study in localized prostate cancer. A review of the biopsy data from the first seven men to complete the study showed that four patients experienced a response to treatment: One patient experienced complete ablation of the tumor where no evidence of the treated tumor remained on a targeted biopsy at 6 months; three patients experienced either a reduction in the maximum cancer core length or a reduction in Gleason pattern; three patients had no response to treatment.

This one-time administration of topsalysin directly into a pre-identified clinically significant tumor appears to be well tolerated with no serious adverse events and no new safety signals being reported. This is consistent with safety observed in the 365 patients that have been treated with topsalysin in the Company's BPH program to date.

The ongoing Phase 2a proof of concept study is a single-center, open-label study at University College London, which is well known for the focal treatment of prostate cancer in the UK. In this study, previously obtained multiparametric magnetic resonance images (mpMRIs) of each patient's prostate tumor lesions are mapped to real-time three-dimensional transrectal ultrasound. These images are used to guide the injection of topsalysin to treat a single, histologically-proven, clinically significant prostate cancer lesion. The primary objective of the study is safety and tolerability, and the key efficacy variable is the change in the treated lesion on targeted biopsy after 6 months. The study is designed to assess whether topsalysin has the potential to provide patients with clinically significant, localized, low to intermediate risk prostate cancer a tissue-sparing cancer treatment that carries little in the way of side effects. A total of 18 patients were enrolled and treated in this study. Sophiris expects to have final data on all patients by the end of the second quarter of 2016.

Certain statements included in this Form 8-K may be considered forward-looking, including expectations about the potential use of topsalysin for the ablation or focal treatment of prostate cancer tumors, statements about the expected timing of completing the ongoing proof of concept study for the treatment of localized low to intermediate risk prostate cancer, expectations that the results of the proof of concept study will be consistent with the results for the first seven patients, expectations that the Company will able to use data from the proof of concept study to develop more effective delivery and dosing protocols 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, risk associated with clinical trial development, including the risks that clinical data from a subset of patients may not be predicative of clinical data observed in subsequent patients or in subsequent clinical trials of the same drug candidate and other 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 in the endeavor of building a business around such treatments. 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 Form 8-K. 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 January 28, 2016.

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: February 1, 2016

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

Exhibit 99.1

Sophiris Bio Reports Encouraging Preliminary Data from Phase 2a Proof of Concept Study in Localized Prostate Cancer

Investor webcast scheduled for today at 11:00 a.m. Pacific Time

SAN DIEGO and VANCOUVER, British Columbia, January 28, 2016 – Sophiris Bio Inc. (NASDAQ: SPHS) (the "Company" or "Sophiris"), a biopharmaceutical company developing PRX302 (topsalysin) for the treatment of urological diseases, today announced the biopsy data at 6 months for the first seven patients to complete the Phase 2a proof-of-concept study in localized prostate cancer.

A review of the biopsy data from the first seven men to complete the study showed that four patients experienced a response to treatment: One patient experienced complete ablation of the tumor where no evidence of the treated tumor remained on a targeted biopsy at 6 months; three patients experienced either a reduction in the maximum cancer core length or a reduction in Gleason pattern; three patients had no response to treatment.

"This new trial is very exciting -- we have promising data showing that topsalysin can ablate cancer cells and we look forward to reviewing the results from the remaining 11 patients as they complete the study. We could be on the cusp of a new class of therapeutics for the focal treatment of localized prostate cancer," stated Professor Mark Emberton, Dean, Faculty of Medical Sciences, University College London and Honorary Consultant Urologist University

College London Hospital NHS Foundation Trust.

Dr. Hashim Ahmed, Principal Investigator for the study, Division of Surgery and Interventional Sciences, University College London, said, “Topsalysin could offer a tissue-sparing cancer treatment that carries little in the way of side effects. This treatment has the potential to help men avoid radical treatments such as radiation therapy or complete removal of the prostate.”

This one-time administration of topsalysin directly into a pre-identified clinically significant tumor appears to be well tolerated with no serious adverse events and no new safety signals being reported. This is consistent with safety observed in the 365 patients that have been treated with topsalysin in the Company’s BPH program to date.

“The biological activity that we have observed further validates the mechanism of action of topsalysin. We are gaining valuable experience on how we might best optimize both the delivery and dose of topsalysin based on lesion size, and the remaining patients to complete the study will help in that assessment,” said Dr. Ahmed.

The ongoing Phase 2a proof of concept study is a single-center, open-label study at University College London, which is well known for the focal treatment of prostate cancer in the UK. In this study, previously obtained multiparametric magnetic resonance images (mpMRIs) of each patient’s prostate tumor lesions are mapped to real-time three-dimensional transrectal ultrasound. These images are used to guide the injection of topsalysin to treat a single, histologically-proven, clinically significant prostate cancer lesion. The primary objective of the study is safety and tolerability, and the key efficacy variable is the change in the treated lesion on targeted biopsy after 6 months. The study is designed to assess whether topsalysin has the potential to provide patients with clinically significant, localized, low to intermediate risk prostate cancer a tissue-sparing cancer treatment that carries little in the way of side effects. A total of 18 patients were enrolled and treated in this study. Sophiris expects to have final data on all patients by the end of the second quarter of 2016.

Webcast scheduled for today at 11:00 a.m. Pacific Time

The Sophiris management team will host a conference call and webcast today, January 28, at 11:00 a.m. Pacific Time to review the topsalysin prostate cancer data as well as the previously announced results of the topsalysin Phase 3 study in BPH. Dr. Hashim Ahmed, University College London and an investigator in the prostate cancer study, and Dr. Marc Gittelman, Director of South Florida Medical Research and investigator in the Phase 3 BPH study, will also participate in the call.

A live audio webcast will be accessible on the "Investor Relations" page of the Sophiris corporate website at . A replay will be available at the same location for 60 days.

About Prostate Cancer

Prostate cancer is the second most common form of cancer in men in the US with an estimated 220,800 new cases in 2015. 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 do 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.

Topsalysin for the Targeted Treatment of Localized Prostate Cancer

Topsalysin (PRX302) has the potential to provide a focal targeted therapy for the ablation of localized prostate cancer while potentially avoiding many of the complications and side effects associated with whole gland radical treatments. The increasing use of multi-parametric magnetic resonance imaging (mpMRI) and advances in mapping previously obtained mpMRI images with real-time three-dimensional ultrasound images enables physicians 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. Topsalysin, an inactivated pore-forming protein, was engineered to be activated only by enzymatically-active PSA, which is present only in prostate tissue. The targeted focal treatment of prostate cancer is in line with current treatments for solid tumors such as breast and liver, where the goal is to remove the tumor and preserve as much of the organ as possible.

About Sophiris

Sophiris Bio Inc. is a biopharmaceutical company developing topsalysin, a clinical-stage, targeted therapy for the treatment of urological diseases. Topsalysin is in Phase 3 clinical development for the treatment of the symptoms of benign prostatic hyperplasia (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. Topsalysin 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 expectations about the potential use of topsalysin for the ablation or focal treatment of prostate cancer tumors, statements about the expected timing of completing the ongoing proof of concept study for the treatment of localized low to intermediate risk prostate cancer, expectations that the results of the proof of concept study will be consistent with the results for the first seven patients, expectations that the Company will able to use data from the proof of concept study to develop more effective delivery and dosing protocols 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, risk associated with clinical trial development, including the risks that clinical data from a subset of patients may not be predicative of clinical data observed in subsequent patients or in subsequent clinical trials of the same drug candidate and other 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 in the endeavor of building a business around such treatments. 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.