

SOPHIRIS BIO INC.

FORM 8-K (Current report filing)

Filed 08/10/17 for the Period Ending 08/10/17

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| Address | 1258 PROSPECT STREET LA JOLLA, CA 92037 |
| Telephone | 858-777-1760 |
| CIK | 0001563855 |
| SIC Code | 2834 - Pharmaceutical Preparations |
| Industry | Pharmaceuticals |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

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 10 , 2017

Date of Report (Date of earliest event reported)

Sophiris Bio Inc .

(Exact name of registrant as specified in its charter)

British Columbia

(State or other jurisdiction
of incorporation)

001-36054

(Commission File Number)

98-1008712

(IRS Employer Identification No.)

**1258 Prospect Street
La Jolla, CA**

(Address of principal executive offices)

92037

(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 2.02 Results of Operations and Financial Condition.

On August 10, 2017, Sophiris Bio Inc. issued a press release announcing its financial results for the three and six months ended June 30, 2017. A copy of this press release is furnished herewith as Exhibit 99.1. Pursuant to the rule and regulations of the Securities and Exchange Commission, such exhibit and the information set forth therein and in this Item 2.02 have been furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing regardless of any general incorporation language.

Item 9.01 Financial Statements and Exhibits .

(d) Exhibits

99.1 Press release dated August 10, 2017.

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 10, 2017

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



Sophiris Bio Reports Second Quarter Financial Results and Key Corporate Highlights

SAN DIEGO and VANCOUVER, British Columbia, August 10 , 201 7 – Sophiris Bio Inc. (NASDAQ: SPHS) (the “Company” or “Sophiris”), a late stage clinical biopharmaceutical company developing topsalysin (PRX302) for the treatment of patients with urological diseases, today reported financial results for the three and six months ended June 30, 2017 and key corporate highlights.

Key Corporate Highlights:

- o **Phase 2b Localized Prostate Cancer Study Underway** . On June 8, 2017, the Company announced that the first patient had been dosed in its Phase 2b study to evaluate the safety and tolerability of a single dose of topsalysin in focally treating men with clinically significant localized prostate cancer. Topsalysin (PRX302) is an innovative, first-in-class pore-forming protein engineered to be activated only in the presence of enzymatically-active PSA, which is only found within the prostate. This study is enrolling approximately 40 patients at clinical sites in the UK and US. The Company expects to receive the 24- week biopsy data for all patients from the first dose of topsalysin in the first quarter of 2018 assuming enrollment is completed as expected.

The Phase 2b study includes an option to re-treat patients with a second dose of topsalysin, with a targeted biopsy to occur 24 weeks following the second dose. The Company expects to have complete data on all patients who receive a second dose by the fourth quarter of 2018 assuming enrollment is completed as expected.

- o **Added to Russell Microcap Index[®]** . In June 2017, the Company was added to the Russell Microcap[®] Index. Russell indices are widely used by investment managers and institutional investors for index funds and as benchmarks for both passive and active investment strategies.
- o **Filing of New Form S-3**. In anticipation of the expiration of the company’s existing Form S-3 shelf registration statement filed in September 2014, Sophiris will file a new Form S-3 today with the Securities and Exchange Commission to register securities which could be issued in the future.

“Topsalysin is a highly potent ablative agent, which we administer by an ultrasound-guided injection directly into a tumor, previously confirmed by biopsy. We are using state of the art commercially available software in order to increase the precision by which the physician administers topsalysin into the pre-identified tumor,” said Randall E. Woods, president and CEO of Sophiris. “We are working toward completion of enrollment, and we would like to thank the investigators, study coordinators and patients for their participation in this exciting study.”

Financial Results :

At June 30, 2017, the Company had cash, cash equivalents and securities available-for-sale of \$24.0 million and working capital of \$23.4 million. The Company expects that its cash and cash equivalents will be sufficient to fund its operations through the end of 2018. The Company is currently not planning on pursuing a second Phase 3 trial in BPH, unless the Company can secure a development partner to fund a new clinical trial or the Company obtains other financing.



For the three months ended June 30, 2017

The Company reported net income of \$0.6 million or \$0.02 per share for the three months ended June 30, 2017 compared to a net loss of \$4.1 million or (\$0.21 per share) for the three months ended June 30, 2016. The net income for the three months ended June 30, 2017 was driven by a non-cash gain related to the revaluation of the Company's warrant liability. See an additional discussion below related to this item.

Research and development expenses

Research and development expenses were \$ 1.4 million for the three months ended June 30, 2017, compared to \$1.0 million for the three months ended June 30, 2016. The increase in research and development costs are primarily attributable to increases in the costs associated with the Company's Phase 2b clinical trial for the focal treatment of localized prostate cancer, costs associated with manufacturing activities for topsalysin and non-cash stock-based compensation expense. These increases are partially offset by decreases in costs associated with our completed Phase 2a proof of concept clinical trial for low to intermediate risk prostate cancer and personnel related costs.

General and administrative expenses

General and administrative expenses were \$1.4 million for the three months ended June 30, 2017 and 2016. General and administrative expense included non-cash stock-based compensation expense of \$0.3 million for the three months ended June 30, 2017 as compared to \$0.1 million for the three months ended June 30, 2016. This increase was offset by decreases for personnel related costs.

Gain (loss) on revaluation of the warrant liability

Gain on revaluation of the warrant liability was \$3.3 million for the three months ended June 30, 2017 compared to a loss of \$1.6 million for the three months ended June 30, 2016. Because these warrants may require us to pay the warrant holder cash under certain provisions of the warrant, we account for these warrants as a liability and we are required to calculate the fair value of these warrants each reporting date. This non-cash gain is associated with a reduction in the fair value of the Company's warrant liability which is calculated using a Black-Scholes pricing model. Certain inputs utilized in the Company's Black-Scholes fair value calculation may fluctuate in future periods based upon factors which are outside of the Company's control. A significant change in one or more of these inputs used in the calculation of the fair value may cause a significant change to the fair value of the Company's warrant liability, which could also result in material non-cash gain or loss being reported in the Company's consolidated statement of operations and comprehensive loss.

For the six months ended June 30, 2017

The Company reported a net loss of \$ 2.0 million or (\$0.07 per share) for the six months ended June 30, 2017 compared to a net loss of \$6.3 million or (\$0.35 per share) for the six months ended June 30, 2016.

Research and development expenses

Research and development expenses were \$ 2.6 million for the six months ended June 30, 2017 compared to \$1.9 million for the six months ended June 30, 2016. The increase in research and development costs are primarily attributable to increases in the costs associated with the Company's Phase 2b for the focal treatment of localized prostate cancer, costs associated with the manufacturing activities for topsalysin and the non-cash stock-based compensation expense. These increases are partially offset by decreases in costs associated with our completed Phase 2a proof of concept clinical trial for low to intermediate risk prostate cancer and personnel related costs.



General and administrative expenses

General and administrative expenses were \$ 2.7 million for the six months ended June 30, 2017 compared to \$2.5 million for the six months ended June 30, 2016. The increase is primarily due to an increase in professional services and non-cash stock-based compensation expense. These increases are partially offset by the decreases in personnel related costs, legal and closing costs which were expensed as they were allocated to the warrants issued in our completed financing during the six months ended June 30, 2016.

Gain (loss) on revaluation of the warrant liability

Gain on revaluation of the warrant liability was \$3.2 million for the six months ended June 30, 2017 as compared to a loss of \$1.6 million for the six months ended June 30, 2016. This non-cash gain is associated with a reduction in the fair value of our warrant liability.

About Sophiris

Sophiris Bio Inc. is a late-stage clinical biopharmaceutical company developing topsalysin (PRX302) for the treatment of patients with urological diseases . Topsalysin is in Phase 2 clinical development for the focal treatment of localized prostate cancer as well as Phase 3 clinical development for the treatment of the lower urinary tract symptoms of benign prostatic hyperplasia (BPH). Topsalysin is a highly potent ablative agent that is selective and targeted in that it is only activated by enzymatically active PSA which is found in high concentrations in the transition zone of the prostate and in and around prostate tumor cells. More than 400 patients have received topsalysin, which continues to appear to be safe and well tolerated. For more information, please visit www.sophirisbio.com.

Certain statements included in this press release may be considered forward-looking, including the quote of Sophiris' President and CEO , expectations about further development of topsalysin (PRX302) , including the timing of expected results , statements about warrant liability and statements related to Sophiris' liquidity or 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 clinical development, including the risk that the enrollment of the Phase 2b study will not be completed when expected and that results will not be available when expected and risks that the results of the Phase 2b study will not replicate the results of the completed Phase 2 study of topsalysin for the treatment of localized low to intermediate risk prostate cancer or the study endpoint[s] will not be achieved , and other risks and uncertainties identified by Sophiris in its public securities filings with the SEC. 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.

Company Contact:

Peter Slover
Chief Financial Officer
(858) 777-1760

Corporate Communications Contact:

Jason Spark
Canale Communications
(619) 849-6005
jason@canalecomm.com



Sophiris Bio Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share amounts)
(Unaudited)

| | <u>June 30 2017</u> | <u>December 31, 2016</u> |
|--|-------------------------|------------------------------|
| Assets: | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 6,824 | \$ 12,800 |
| Securities available-for-sale | 17,205 | 16,201 |
| Other receivables | 69 | 128 |
| Prepaid expenses | 948 | 846 |
| Total current assets | 25,046 | 29,975 |
| Property and equipment, net | 2 | 4 |
| Other long-term assets | - | 19 |
| Total assets | \$ 25,048 | \$ 29,998 |
| Liabilities and shareholders' equity: | | |
| Current liabilities: | | |
| Accounts payable | \$ 506 | \$ 459 |
| Accrued expenses | 1,154 | 1,762 |
| Total current liabilities | 1,660 | 2,221 |
| Warrant liability | 10,162 | 13,396 |
| Stock-based compensation liability | - | 57 |
| Total liabilities | 11,822 | 15,674 |
| Shareholders' equity: | | |
| Common shares, unlimited authorized shares, no par value; 30,111,153 and 30,107,644 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively | 131,246 | 131,245 |
| Contributed surplus | 24,824 | 23,900 |
| Accumulated other comprehensive gain | 85 | 99 |
| A ccumulated deficit | (142,929) | (140,920) |
| Total shareholders' equity | 13,226 | 14,324 |
| Total liabilities and shareholders' equity | \$ 25,048 | \$ 29,998 |



Sophiris Bio Inc.
Condensed Consolidated Statement s of Operations and Comprehensive Income (Loss)
(In thousands, except per share amounts)
(Unaudited)

| | <u>Three Months Ended June 30 ,</u> | | <u>Six Months Ended June 30,</u> | |
|--|-------------------------------------|-------------------|----------------------------------|-------------------|
| | <u>2017</u> | <u>2016</u> | <u>2017</u> | <u>2016</u> |
| Operating expenses: | | | | |
| Research and development | \$ 1,387 | \$ 978 | \$ 2,595 | \$ 1,907 |
| General and administrative | 1,367 | 1,357 | 2,736 | 2,521 |
| Total operating expenses | <u>2,754</u> | <u>2,335</u> | <u>5,331</u> | <u>4,428</u> |
| Other income (expense): | | | | |
| Interest expense | - | (137) | - | (287) |
| Interest income | 53 | 3 | 103 | 7 |
| Gain (Loss) on revaluation of warrant liability | 3,320 | (1,619) | 3,234 | (1,619) |
| Other expense , net | (9) | (3) | (16) | (7) |
| Total other income (expense) | <u>3,364</u> | <u>(1,756)</u> | <u>3,321</u> | <u>(1,906)</u> |
| Net income (loss) | <u>\$ 610</u> | <u>\$ (4,091)</u> | <u>\$ (2,010)</u> | <u>\$ (6,334)</u> |
| Basic income (loss) per share | <u>\$ 0.02</u> | <u>\$ (0.21)</u> | <u>\$ (0.07)</u> | <u>\$ (0.35)</u> |
| D iluted income (loss) per share | <u>\$ 0.02</u> | <u>\$ (0.21)</u> | <u>\$ (0.07)</u> | <u>\$ (0.35)</u> |
| Weighted average number of outstanding shares – basic | <u>30,111</u> | <u>19,340</u> | <u>30,111</u> | <u>18,292</u> |
| Weighted average number of outstanding shares –diluted | <u>30,515</u> | <u>19,340</u> | <u>30,111</u> | <u>18,292</u> |

Source: Sophiris Bio Inc.