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Sophiris Bio Inc. (SPHS-NASDAQ)

SPHS: Awaiting Feedback from FDA on Phase 3 Plan for Topsalysin in Prostate Cancer…

Based on our probability adjusted DCF model that takes into account potential future revenues from topsalysin in both BPH and prostate cancer, SPHS is valued at $5/share. This model is highly dependent upon the clinical success of topsalysin and will be adjusted accordingly based upon future clinical results.

Current Price (08/27/19)	$0.95
Valuation	**$5.00**

OUTLOOK

On August 9, 2019, Sophiris Bio Inc. (SPHS) announced financial results for the second quarter of 2019 and provide a business update. During the second quarter, the company received positive feedback from the European Medicines Agency (EMA) on the company's prosposed Phase 3 clinical trial plan for topsalysin in prostate cancer. It will be a multicenter, randomized trial of approximately 700 men with localized, intermediate risk prostate cancer who will be randomized 1:1 to receive a single injection of either topsalysin or placebo. The primary endpoint of the trial will be the percentage of patients with histological progression at 12 months that requires an alternative treatment. The company is currently engaged with the FDA on the design of the Phase 3 trial, with the goal being to conduct a single trial that, if successful, will provide the clinical data necessary to seek approval in both the U.S. and E.U.

The company is continuing to evaluate the best means by which to fund the trial, which may include a development partnership or other strategic transaction.

SUMMARY DATA

52-Week High	**$3.23**
52-Week Low	**$0.71**
One-Year Return (%)	**-63.49**
Beta	**2.86**
Average Daily Volume (sh)	**77,189**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$29**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-2.7**
P/E using 2019 Estimate	**-2.4**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 A	0 A	0 E	0 E	0 E
2020					0 E
2021					0 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.11 A	-$0.20 A	-$0.10 A	$0.18 A	-$0.23 A
2019	-$0.08 A	-$0.07 A	-$0.09 E	-$0.08 E	-$0.32 E
2020					-$0.36 E
2021					-$0.39 E

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WHAT'S NEW

Business Update

Sophiris Bio Inc. (SPHS) is developing treatments for localized clinically significant prostate cancer and lower urinary tract symptoms of benign prostatic hyperplasia (BPH). The company's lead candidate, topsalysin (PRX302), is a genetically engineered recombinant protein that is activated through enzymatic cleavage by prostate specific antigen (PSA), which is produced in large quantities by the prostate gland. Once activated, topsalysin self-aggregates to form stable transmembrane pores and initiate cell death. The compound showed a 27% response rate in a Phase 2b clinical trial in patients with localized clinically significant prostate cancer and Sophiris is currently preparing for a Phase 3 clinical trial.

Positive Feedback from the EMA Regarding Phase 3 Trial Design

On June 19, 2019, Sophiris announced positive feedback from the European Medicines Agency (EMA) regarding the Phase 3 clinical trial design for topsalysin in localized prostate cancer. Based on this feedback, we believe a single successful Phase 3 trial will support approval by the EMA. It will be a multicenter, randomized trial that will enroll approximately 700 men with localized intermediate risk prostate cancer. Patients will be randomized 1:1 to receive either a single injection of topsalysin or placebo. The primary endpoint of the trial is the percentage of patients who exhibit histological progression at 12 months that requires an alternative treatment. Key secondary endpoints include safety and tolerability, with an emphasis on a comparison with the safety and tolerability of more invasive treatments.

While the total number of centers participating has yet to be finalized, we anticipate the trial will include centers in the both the U.S. and the E.U. Based on the company's past experience with a similar sized trial for benign prostate hyperplasia (BPH), we estimate that it will take approximately nine to 12 months to fully enroll 700 patients. The company is still determining the optimal means of funding the trial, which may include a development partnership or other type of strategic transaction.

Phase 2b Clinical Trial Results

The final results for the Phase 2b clinical trial were announced in Dec. 2018. A total of 38 patients received a single administration of topsalysin to treat a clinically significant tumor, which was defined for this study as either a Gleason score of 6 (pattern 3 + 3) and greater than or equal to 6 mm maximum cancer core length (MMCL), or a Gleason score of 7 (pattern 3 + 4) and less than or equal to 10 mm MCCL. Ten patients received a second administration of topsalysin due to having a partial response to the first treatment, however their lesions were still clinically significant.

Following a single administration of topsalysin, 10/37 (27%) patients had a clinical response, defined in this study as no detectable tumor or a sufficient reduction to deem the tumor clinically insignificant (Gleason score of 6 and MCCL of less than 6 mm). In addition, 15/37 (41%) patients had a partial response, which was defined as a reduction in Gleason pattern and/or MCCL, however the target lesion was still clinically significant. A total of 32% (12/37) of patients had no response to treatment, which was defined as no change in the targeted lesion or an increase in Gleason pattern and/or MCCL.

Six-month biopsy data for the 10 patients that received a second administration of topsalysin showed it to be safe and well tolerated, however there was no additional clinical benefit seen. While there were no complete ablations following the second administration, some patients did have a partial response in the form of a smaller lesion size, however the tumors were still considered clinically significant. A potential reason for the lack of efficacy in the second dose could be due to the fact that some of the patients received less than 500 μg of topsalysin in the second dose due to the tumor having been reduced in size following the first administration. Data from the Phase 2a trial showed that most of the responders in that study received > 500 μg topsalysin while most of the non-responders received < 500 μg topsalysin.

The most important findings from the Phase 2b trial are that it can potentially offer between one-quarter and one-third of patients with clinically significant localized prostate cancer the chance to delay or avoid a more invasive procedure to treat that cancer, topsalysin is safe and well tolerated, and, in comparison to other treatments,

topsalysin has much fewer potential side effects including no effect on urine function and no sexual dysfunction.

Financial Update

On August 9, 2019, Sophiris Bio Inc. (SPHS) announced financial results for the second quarter of 2019. As expected, the company did not report any revenues. The company reported a net loss of $2.2 million, or $0.07 per share, for the second quarter of 2019 compared to a net loss of $6.1 million, or $0.20 per share, for the second quarter of 2018. R&D expenses in the second quarter of 2019 were $1.1 million compared to $3.6 million in the second quarter of 2018. The decrease was primarily due to decreased manufacturing activities for topsalysin and clinical trial costs associated with the Phase 2b clinical trial. G&A expenses for the second quarter of 2019 were $1.2 million compared to $1.1 million for the second quarter of 2018. Gain on revaluation of the warrant liability was $0.3 million in the second quarter of 2019 compared to a loss of $1.4 million for the second quarter of 2018. The non-cash gain is due to a change in the fair value of the warrant liability using a Black-Scholes pricing model.

As of June 30, 2019, Sophiris had approximately $6 million in cash, cash equivalents, and short-term investments. On August 27, 2019 the company announced a $4 million registered direct offering. Following the offering, we estimate that the company has sufficient capital to obtain formal feedback from the FDA and finalize the Phase 3 strategy, however the company will require significant additional funding to advance topsalysin in clinical development. We estimate that following the offering the company has approximately 35.5 million common shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 49.6 million.

Conclusion

Sophiris has a plan in place to advance topsalysin to a pivotal Phase 3 clinical trial, and thus far the company is executing well on that plan. The positive feedback from the EMA is encouraging and the company is now putting the final details into place to be able to initiate the trial later this year or early next year. The company is currently engaged in discussion with the FDA regarding the Phase 3 trial design, and we anticipate an update regarding those discussions later this year. We also anticipate the company entering into some type of partnership or other strategic transaction in order to initiate the Phase 3 trial. We believe a treatment for localized clinically significant prostate cancer with few side effects that could delay or even help avoid more invasive procedures would be a welcome addition to the treatment options for those patients. Given the increased share count following the offering our valuation has decreased to $5 per share.

PROJECTED FINANCIALS

Sophiris Bio, Inc.	2018 A	Q1 A	Q2 A	Q3 E	Q4 E	2019 E	2020 E	2021 E
Topsalysin BPH	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth		-	-	-	-			
Topsalysin Prostate Cancer	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth		-	-	-	-			
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth		-	-	-	-			
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth		-	-	-	-			
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin		-	-	-	-			
Research & Development	$10.7	$1.6	$1.1	$1.5	$1.6	$5.7	$8.0	$10.0
General & Administrative	$4.4	$1.3	$1.2	$1.2	$1.2	$4.8	$5.0	$5.5
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($15.1)	($2.8)	($2.3)	($2.7)	($2.8)	($10.6)	($13.0)	($15.5)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	$8.4	$0.4	$0.1	($0.1)	($0.1)	$0.4	($0.5)	($0.5)
Pre-Tax Income	($6.8)	($2.4)	($2.2)	($2.8)	($2.9)	($10.2)	($13.5)	($16.0)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($6.8)**	**($2.4)**	**($2.2)**	**($2.8)**	**($2.9)**	**($10.2)**	**($13.5)**	**($16.0)**
Net Margin		-	-	-	-			
Reported EPS	**($0.23)**	**($0.08)**	**($0.07)**	**($0.09)**	**($0.08)**	**($0.32)**	**($0.36)**	**($0.39)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	30.1	30.2	30.2	30.2	35.0	31.4	38.0	41.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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