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Sophiris Bio Inc. (SPHS-NASDAQ)

SPHS: Awaiting Regulatory Guidance for Topsalysin Phase 3 Study…

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 $8/share. This model is highly dependent upon the clinical success of topsalysin and will be adjusted accordingly based upon future clinical results.

Current Price (03/29/19)	$1.00
Valuation	**$8.00**

OUTLOOK

On March 13, 2019, Sophiris Bio Inc. (SPHS) announced financial results for the fourth quarter and full year 2019 and provided a business update. Sophiris is awaiting regulatory guidance from the European Medicines Agency (EMA) regarding the company's proposed Phase 3 clinical trial of topsalysin for localized prostate cancer. We anticipate the company receiving this feedback in the second quarter of 2019. Following that, Sophiris is planning to meet with the U.S. Food and Drug Administration (FDA) to finalize plans for the Phase 3 trial. The company exited 2018 with approximately $12.5 million in cash and cash equivalents, however it will require significant additional funding for the Phase 3 trial, which may come in the form of a partnership or other strategic transaction.

SUMMARY DATA

52-Week High	**$3.83**
52-Week Low	**$0.78**
One-Year Return (%)	**-50.25**
Beta	**2.94**
Average Daily Volume (sh)	**149,079**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$30**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**6**
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	**-2.5**
P/E using 2019 Estimate	**-2.2**

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 E	0 E	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	-$0.12 E	-$0.13 E	-$0.14 E	-$0.14 E	-$0.53 E
2020					-$0.56 E
2021					-$0.53 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.

Awaiting Regulatory Guidance on Phase 3 Trial

Sophiris has initiated discussions with the European Medicines Agency (EMA) regarding the design for the Phase 3 clinical trial of topsalysin in localized clinically significant prostate cancer. We anticipate the company announcing receipt of that guidance in the second quarter of 2019. Following that, the company will be meeting with the U.S. Food and Drug Administration (FDA) to ensure that the trial design aligns with both regulatory bodies. Assuming that meeting can take place during the summer of 2019, we believe the company can initiate the Phase 3 study in the fourth quarter of 2019 or first quarter of 2020, subject to obtaining the necessary funding or entering into a strategic partnership.

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.

While working on the Phase 3 trial design, the company is also actively engaged in partnership discussions, as that or another strategic transaction is the most ideal funding option currently available for the Phase 3 trial. Sophiris' current cash total will fund operations through the third quarter of 2019, but the company will require significant additional capital in order to fund the Phase 3 trial.

Financial Update

On March 13, 2019, Sophiris announced financial results for the fourth quarter and full year 2018. As expected, the company did not report any revenues for the fourth quarter or full year 2018. For the fourth quarter of 2018, Sophiris reported net income of $5.5 million, or $0.18 per share, compared to a net loss of $4.0 million, or $0.13 per share, for the fourth quarter of 2017. The net income was driven by a large, non-cash gain related to the revaluation of the company's warrant liability. Research and development expenses were $2.0 million for the fourth quarter of 2018 compared to $1.9 million for the fourth quarter of 2017. The increase in R&D expenses was primarily due to increased costs associated with topsalysin manufacturing offset in part by a decrease in personnel related costs. General and administrative expenses were $0.9 million for the fourth quarter of 2018 compared to $1.3 million for the fourth quarter of 2017. The decrease was primarily due to decreases in personnel related expenses and marketing research activities. The company reported a non-cash gain on revaluation of the warrant liability of $8.5 million in the fourth quarter of 2018 compared to a loss on the revaluation of the warrant liability of $0.6 million for the fourth quarter of 2017.

For 2018, Sophiris reported a net loss of $6.8 million, or $0.23 per share, compared to a net loss of $8.6 million or $0.29 per share, for 2016. R&D expenses in 2018 were $10.7 million, compared to $6.2 million for 2017. The increase was primarily due to increased costs associated with topsalysin manufacturing. G&A expenses for 2018 were $4.4 million compared to $5.7 million in 2017. The decrease was primarily due to decreases in non-cash stock-based compensation, marketing research activities, and personnel costs.

The company exited 2018 with approximately $12.5 million in cash and cash equivalents. We believe Sophiris' current cash is sufficient to fund operations through the third quarter of 2019. As of March 4, 2019, Sophiris had approximately 30.2 million common shares outstanding and when factoring in options and warrants a fully diluted share count of approximately 39.0 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. We look forward to learning additional details about the upcoming Phase 3 trial once feedback is received from the EMA. We anticipate the company entering into some type of partnership or other strategic transaction in order to initiate the Phase 3 trial, but do not anticipate partnership talks finishing until after regulatory guidance is received. 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. Our valuation remains $8 per share.

PROJECTED FINANCIALS

Sophiris Bio, Inc.	2018 A	Q1 E	Q2 E	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	$2.5	$2.7	$2.9	$3.0	$11.1	$14.0	$15.0
General & Administrative	$4.4	$1.0	$1.1	$1.2	$1.2	$4.5	$5.0	$5.5
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($15.1)	($3.5)	($3.8)	($4.1)	($4.2)	($15.6)	($19.0)	($20.5)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	$8.4	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.5)	($0.5)
Pre-Tax Income	($6.8)	($3.6)	($3.9)	($4.2)	($4.3)	($16.0)	($19.5)	($21.0)
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)**	**($3.6)**	**($3.9)**	**($4.2)**	**($4.3)**	**($16.0)**	**($19.5)**	**($21.0)**
Net Margin		-	-	-	-			
Reported EPS	**($0.23)**	**($0.12)**	**($0.13)**	**($0.14)**	**($0.14)**	**($0.53)**	**($0.56)**	**($0.53)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	30.1	30.1	30.1	30.1	30.1	30.1	35.0	40.0

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

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