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Sophiris Bio Inc. (SPHS-NASDAQ)

SPHS: Single Phase 3 Clinical Trial Planned for Topsalysin in Localized 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 $3/share. This model is highly dependent upon the clinical success of topsalysin and will be adjusted accordingly based upon future clinical results.

Current Price (11/18/19)	$0.43
Valuation	**$3.00**

OUTLOOK

On October 21, 2019, Sophiris Bio, Inc. (SPHS) announced that the U.S. FDA has agreed to the design of a single Phase 3 clinical trial for topsalysin in localized prostate cancer. The study design agreed upon with the FDA is consistent with what was previously agreed upon with the EMA. It will enroll approximately 700 patients with localized intermediate risk prostate cancer equally randomized to receive a single dose of either topsalysin or placebo. The primary endpoint will be the proportion of patients who have failed treatment at 12 months, meaning that alternative therapy was required. In order to conduct this study, the company will need to receive significant additional financing, which could come in the form of an equity financing, partnership, or merger agreement.

SUMMARY DATA

52-Week High	**$2.15**
52-Week Low	**$0.43**
One-Year Return (%)	**-78.04**
Beta	**2.88**
Average Daily Volume (sh)	**265,811**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$15**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**7**
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	**-1.4**
P/E using 2019 Estimate	**-1.4**

Risk Level	**Above Avg.**
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 A	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	-$0.03 A	-$0.09 E	-$0.27 E
2020					-$0.34 E
2021					-$0.32 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.

Planning for One Phase 3 Trial for Topsalysin in Localized Prostate Cancer

On Oct. 21, 2019, Sophiris announced a positive 'End-of-Phase 2' meeting with the FDA in which the agency agreed in principle to the design of a single Phase 3 clinical trial for topsalysin in patients with intermediate risk localized prostate cancer. This follows an announcement in June 2019 in which the company stated the EMA agreed that a single successful Phase 3 trial will support regulatory approval of topsalysin in localized intermediate risk prostate cancer.

The trial will be a multicenter, randomized, double blind study that will enroll approximately 700 men with localized intermediate risk prostate cancer. Patients will be randomized 1:1 to receive a single dose of either topsalysin or placebo. The primary endpoint will be the percentage of patients that require an alternative therapy at 12 months. Key secondary endpoints include safety and tolerability, with an emphasis on a comparison with the safety and tolerability of more invasive treatments. The FDA also indicated that Sophiris will need to monitor all patients that progress to alternative treatments for an additional 12 months, for a total of 24 months of data, following administration of the drug.

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 November 8, 2019, Sophiris Bio announced financial results for the third quarter of 2019. As expected, the company did not report any revenues. Sophiris reported a net loss of $1.0 million, or $0.03 per share, for the third quarter of 2019 compared to a net loss of $2.9 million, or $0.10 per share, for the third quarter of 2018. R&D expenses for the third quarter of 2019 were $0.7 million compared to $1.8 million for the third quarter of 2018. The decrease was due to decreased manufacturing and clinical costs. G&A expenses were $1.4 million for the third quarter of 2019 compared to $1.2 million for the third quarter of 2018. The increase was due to offering costs allocated to the warrants issued during the August 2019 financing. Gain on revaluation of the warrant liability was $1.3 million for the third quarter of 2019 compared to $0.2 million for the third 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 Sep. 30, 2019, Sophiris had approximately $6.3 million in cash, cash equivalents, and short-term investments. On August 27, 2019 the company announced a registered direct offering in which the company raised net proceeds of $3.6 million. We estimate that Sophiris has sufficient capital to fund operations through the end of the first quarter of 2020, however the company will require significant additional capital in order to finance the Phase 3 clinical trial of topsalysin, which the company may acquire through an equity offering, a partnership, or merger agreement.

As of Nov. 3, 2019, Sophiris had approximately 34.5 million shares of common stock outstanding and when factoring in options and warrants a fully diluted share count of approximately 48.6 million.

Conclusion

We are glad to see that the FDA has agreed that a single successful Phase 3 clinical trial for topsalysin in localized intermediate risk prostate cancer can serve as the basis for seeking approval. In order to conduct the trial, the company is going to need a substantial influx of capital, and we anticipate that the most likely route for this will be through a partnership or some other type of strategic transaction.

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. Based on the estimated funding needed to conduct the Phase 3 trial and the dilution that would be required to attain that funding we have decreased our fair value to $3 per share.

PROJECTED FINANCIALS

Sophiris Bio, Inc.	2018 A	Q1 A	Q2 A	Q3 A	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	$0.7	$1.6	$5.0	$8.0	$10.0
General & Administrative	$4.4	$1.3	$1.2	$1.4	$1.2	$5.1	$5.0	$5.5
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($15.1)	($2.8)	($2.3)	($2.1)	($2.8)	($10.0)	($13.0)	($15.5)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	$8.4	$0.4	$0.1	$1.2	($0.1)	$1.7	($0.5)	($0.5)
Pre-Tax Income	($6.8)	($2.4)	($2.2)	($1.0)	($2.9)	($8.4)	($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)**	**($1.0)**	**($2.9)**	**($8.4)**	**($13.5)**	**($16.0)**
Net Margin		-	-	-	-			
Reported EPS	**($0.23)**	**($0.08)**	**($0.07)**	**($0.03)**	**($0.09)**	**($0.27)**	**($0.34)**	**($0.32)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	30.1	30.2	30.2	32.1	32.5	31.2	40.0	50.0

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

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