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Sophiris Bio Inc. (SPHS-NASDAQ)

SPHS: Patient Death in Phase 2b Trial Unlikely Related to Topsalysin Treatment…

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 (08/30/18)	$3.19
Valuation	**$8.00**

OUTLOOK

On August 29, 2018, Sophiris Bio Inc. (SPHS) announced that following an investigation into the patient death in the ongoing Phase 2b clinical trial of topsalysin it was determined the death is unlikely related to topsalysin or the dosing procedure. This conclusion comes following a comprehensive review of the patients autopsy report along with hospital records and tests for acute hypersensitivity. The official autopsy finding was for Sudden Cardiac Death probably due to arrhythmia and the patient had a number of risk factors for SCD. The study investigator that treated the patient concurs with the conclusion that the patient death was unlikely related to topsalysin or the procedure.

The complete safety and efficacy data from the study will be reported before the end of 2018, and will include data from the 10 patients that received a second administration of topsalysin.

SUMMARY DATA

52-Week High	**$3.83**
52-Week Low	**$1.89**
One-Year Return (%)	**45.00**
Beta	**1.37**
Average Daily Volume (sh)	**457,183**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$96**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
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	**-5.9**
P/E using 2019 Estimate	**-5.8**

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)
2017	0 A	0 A	0 A	0 A	0 A
2018	0 A	0 A	0 E	0 E	0 E
2019					0 E
2020					0 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.09 A	$0.02 A	-$0.09 A	-$0.11 A	-$0.29 A
2018	-$0.11 A	-$0.20 A	-$0.16 E	-$0.16 E	-$0.64 E
2019					-$0.57 E
2020					-$0.56 E

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Business Update

Patient Death Unlikely Related to Topsalysin Treatment

On August 29, 2018, Sophiris Bio, Inc. (SPHS) announced the result of an investigation into the previously announced patient death in the ongoing Phase 2b trial of topsalysin (PRX302) in localized clinically significant prostate cancer. After reviewing the autopsy report, hospital records, and hypersensitivity tests, it was determined that the patient's death was unlikely the result of topsalysin or the procedure. The official cause of death listed on the autopsy report is Sudden Cardiac Deach (SCD) probably due to arrhythmia and the patient had a number of risk factors for SCD. The investigator that treated the patient concurs with the conclusion that the patient's death was unlikely related to topsalysin or the procedure. The study is ongoing and we anticipate full efficacy and safety results, including on the 10 patients that received a second dose of topsalysin, before the end of 2018.

Interim Safety and Efficacy Data for Phase 2b Trial of Topsalysin in Localized Prostate Cancer

On June 25, 2018, Sophiris announced interim topline safety and efficacy data for the company's Phase 2b clinical trial of topsalysin in patients with localized clinically significant prostate cancer. 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.

Six months following administration of topsalysin each patient received a follow-up biopsy. The initial data included 35/38 patients that received the follow-up biopsy and evaluation and since that data was reported two more patients have received biopsies with the company expected to announce results from those when they are received. Results showed that 10/35 (29%) 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, 13/35 (37%) 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 34% (12/35) 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. These results compare favorably to the results seen in the company's P2a study of topsalysin in which 3/18 (17%) of patients had a clinical response.

On the conference call to discuss the results, Dr. Hashim Ahmed, the study's principal investigator, stated that the goal heading into this trial was to achieve a clinical response rate of 30%. Thus, if these results were to be replicated in a Phase 3 registration study, topsalysin could potentially help approximately 1/3rd of men with clinically significant localized prostate cancer delay or perhaps avoid more invasive treatment options.

Topsalysin delivery was performed using a spring needle such that the drug could be administered slowly, thus allowing it to diffuse around the tumor cells and surrounding regions. This was one of the most significant changes between the Phase 2a and 2b trials. However, even using this method there continues to be room for improvement in the delivery of topsalysin as some tumors may require more than the 6 mL that was used in order to fully saturate the tumor.

Dr. Ahmed was the sole treating physician in the Phase 2a study, and he stated that he was pleased with the performance of the trial at the other seven centers in the Phase 2b trial and the small learning curve required for physicians to become proficient at administering topsalysin.

Safety Data

Topsalysin continues to show a favorable safety profile and it was well tolerated in the current trial. Adverse events in the Phase 2b trial related to topsalysin included dysuria (n=3), urinary retention (n=3), nocturia (n=2), micturition urgency (n=2), and strangury (n=2). One of the cases of micturition urgency was rated as severe, however it resolved the same day. One case of urinary retention was labeled as moderate and resolved through transurethral resection of the prostate. That patient was also suffering from benign prostatic hyperplasia (BPH), thus that outcome is not all that surprising. All other adverse events were mild with some resolving on the same day.

Sophiris reported that a patient passed away on the same day as receiving a second administration of topsalysin. The cause of death is currently under investigation, however as a precaution the company ceased administration of a second dose of topsalysin. Thus far, over 450 patients have been safely administered topsalysin at various doses, including 10 patients from the Phase 2b study who had already received a second dose. Once the cause of the patient's death is determined, the company will be able to determine the potential for re-administration of topsalysin in future clinical trials.

During the conference call to discuss the results, management was asked whether any multiple dose pre-clinical studies had been performed and if those results could help indicate what may have occurred to the patient that died. Management stated that pre-clinical multiple dose studies had been performed in monkeys and gave no indication that re-administration of topsalysin was associated with any additional adverse events.

Financial Update

On August 14, 2018, Sophiris announced financial results for the second quarter of 2018. As expected, the company did not report any revenues. For the second quarter of 2018, Sophiris reported a net loss of $6.1 million, or $0.20 per share, compared to a net income of $0.6 million, or $0.02 per share, for the second quarter of 2017. The net income in 2017 was due to a non-cash gain related to the revaluation of Sophiris' warrant liability. Research and development expenses were $3.6 million for the second quarter of 2018 compared to $1.4 million for the second quarter of 2017. The increase in R&D expenses was primarily due to increased manufacturing costs for topsalysin along with an increase in clinical costs associated with the Phase 2b clinical trial. G&A expenses were $1.1 million for the second quarter of 2018 compared to $1.4 million for the first quarter of 2017. The decrease was primarily due to decreased stock-based compensation.

As of June 30, 2018, Sophiris had approximately $18.5 million in cash, cash equivalents, and short-term securities. We believe Sophiris' current cash is sufficient to fund operations through the second quarter of 2019, which is after the expected final data from the Phase 2b trial. As of August 10, 2018, Sophiris had approximately 30.1 million common shares outstanding and when factoring in options and warrants a fully diluted share count of approximately 38.8 million.

Conclusion

We are encouraged by the data reported thus far for the Phase 2b study. The clinical response rate has improved compared to the Phase 2a study, and there are an additional 10 patients who will have a second targeted biopsy performed to determine if a second administration of topsalysin can improve the results seen thus far. We anticipate those results before the end of 2018.

The company is currently preparing for meetings with the FDA and EMA, and with the data from the 10 patients administered a second dose of topsalysin expected near the end of 2018, we believe the company will have determined a path forward (which we think will require only one Phase 3 trial) by the end of the first half of 2019.

As we had previously speculated, it doesn't appear that topsalysin or the procedure to administer it were involved in the patient death. Based on this, we have increased the probability of approval for topsalysin to 60%, which has resulted in an increase in our valuation to $8 per share.

PROJECTED FINANCIALS

Sophiris Bio, Inc.	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E	2020 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	$6.2	$3.3	$3.6	$3.5	$3.5	$13.9	$14.0	$14.0
General & Administrative	$5.7	$1.2	$1.1	$1.2	$1.2	$4.7	$5.0	$5.5
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($11.9)	($4.6)	($4.7)	($4.7)	($4.7)	($18.7)	($19.0)	($19.5)
Operating Margin	-	-	-	-	-			
Non-Operating Expenses (Net)	$3.3	$1.2	($1.4)	($0.2)	($0.2)	($0.6)	($0.5)	($0.5)
Pre-Tax Income	($8.6)	($3.3)	($6.1)	($4.9)	($4.9)	($19.2)	($19.5)	($20.0)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($8.6)**	**($3.3)**	**($6.1)**	**($4.9)**	**($4.9)**	**($19.2)**	**($19.5)**	**($20.0)**
Net Margin	-	-	-	-	-			
Reported EPS	**($0.29)**	**($0.11)**	**($0.20)**	**($0.16)**	**($0.16)**	**($0.64)**	**($0.57)**	**($0.56)**
YOY Growth	-	-	-	-	-			
Basic Shares Outstanding	30.1	30.1	30.1	30.1	30.1	30.1	34.0	36.0

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

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