Zacks Small-Cap Research

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Sophiris Bio Inc. (SPHS-NASDAQ)

SPHS: Interim Data Reported for P2b Study of 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 $6/share. This model is highly dependent upon the clinical success of topsalysin and will be adjusted accordingly based upon future clinical results.

Current Price (07/12/18)	$3.07
Valuation	**$6.00**

OUTLOOK

On June 25, 2018, Sophiris Bio Inc. (SPHS) announced topline interim safety and biopsy data for the company's Phase 2b study of topsalysin in localized prostate cancer. Following a single administration of topsalysin, 10 of 35 patients (29%) demonstrated a clinical response, including six patients that had complete ablation of the tumor.

Sophiris was recently informed of a patient death that occurred on the same day as their second administration of topsalysin. The cause of death is currently unknown, but as a precaution no additional patients will receive a second dose of the drug (although 10 patients had already received a second administration prior to this event). We anticipate learning additional details about the patient's death in the coming weeks.

SUMMARY DATA

52-Week High	**$3.83**
52-Week Low	**$1.82**
One-Year Return (%)	**44.13**
Beta	**1.41**
Average Daily Volume (sh)	**957,073**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$92**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
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 E	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	-$0.11 E	-$0.11 E	-$0.12 E	-$0.45 E
2019					-$0.40 E
2020					-$0.39 E

WHAT'S NEW

Business Update

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

On June 25, 2018, Sophiris Bio, Inc. (SPHS) announced interim topline safety and efficacy data for the company's Phase 2b clinical trial of topsalysin (PRX302) 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. Thus far, 35/38 patients have received the follow-up biopsy and evaluation with two more biopsies scheduled to occur in the next few weeks. 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 was recently informed 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 has 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, 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.

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.

In addition, we anticipate learning more about the circumstances surrounding the patient death in the coming weeks, something that investors should keep a very close eye on. At this point we think it is unlikely that the death will be drug related, which we base on the fact that topsalysin has been safely administered to over 450 patients thus far and there was no indication of adverse events related to repeat administrations from preclinical studies. Even if the company does not move forward with repeat administrations, we believe there is compelling enough data to support the single use of topsalysin and advance the program into a pivotal Phase 3 study.

We are sticking with our current valuation of $6 per share pending the investigation into the patient death, and note that if it is determined the patient died from causes unrelated to treatment our valuation is likely to increase based upon the Phase 2b results, with additional upside to those results possible pending the biopsy analysis for those that received a second dose.

PROJECTED FINANCIALS

Sophiris Bio, Inc.	2017 A	Q1 A	Q2 E	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	$1.7	$1.7	$1.7	$8.4	$7.0	$7.3
General & Administrative	$5.7	$1.2	$1.4	$1.5	$1.6	$5.7	$6.0	$6.1
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($11.9)	($4.6)	($3.1)	($3.2)	($3.3)	($14.1)	($13.0)	($13.4)
Operating Margin	-	-	-	-	-			
Non-Operating Expenses (Net)	$3.3	$1.2	($0.2)	($0.2)	($0.2)	$0.6	($0.5)	($0.5)
Pre-Tax Income	($8.6)	($3.3)	($3.3)	($3.4)	($3.5)	($13.5)	($13.5)	($13.9)
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)**	**($3.3)**	**($3.4)**	**($3.5)**	**($13.5)**	**($13.5)**	**($13.9)**
Net Margin	-	-	-	-	-			
Reported EPS	**($0.29)**	**($0.11)**	**($0.11)**	**($0.11)**	**($0.12)**	**($0.45)**	**($0.40)**	**($0.39)**
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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