Zacks Small-Cap Research

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Sophiris Bio Inc. (SPHS-NASDAQ)

SPHS: Ready to Move Topsalysin into Phase 3 for Localized Clinically Significant 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 $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 (12/19/18)	$1.07
Valuation	**$8.00**

OUTLOOK

On December 17, 2018, Sophiris Bio Inc. (SPHS) provided an update on the Phase 2b clinical trial of topsalysin (PRX302) in men with localized clinically significant prostate cancer. Included in the update were topline results from a six-month biopsy in subjects who received a second administration of topsalysin. Those results showed that a second administration of topsalysin is safe and well tolerated, however there was no additional clinical benefit. As previously announced, following a single administration of topsalysin, 10 of 37 patients (27%) demonstrated a clinical response, including six patients that had complete ablation of the tumor. In addition, 15 of 37 patients (41%) were considered partial responders. The company is now preparing to move forward to a Phase 3 program and will be meeting with European and U.S. regulatory authorities once the details of the clinical trial design have been established. We anticipate those meetings taking place in early 2019.

SUMMARY DATA

52-Week High	**$3.83**
52-Week Low	**$1.07**
One-Year Return (%)	**-52.02**
Beta	**1.91**
Average Daily Volume (sh)	**380,408**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$32**
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	**-2.5**
P/E using 2019 Estimate	**-2.2**

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)
2017	0 A	0 A	0 A	0 A	0 A
2018	0 A	0 A	0 A	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	-$0.10 A	-$0.16 E	-$0.57 E
2019					-$0.49 E
2020					-$0.44 E

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WHAT'S NEW

Business Update

Update on Topsalysin Phase 2b Clinical Trial

On December 17, 2018, Sophiris Bio Inc. (SPHS) provided an update for the 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. 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.

The company had previously announced six-month biopsy data for patients who received a single administration of topsalysin. Results showed that 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. During the conference call to discuss the results, management indicated that 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. Management also indicated that 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 company is continuing to evaluate the results and we anticipate the full data set from the Phase 2b study being presented at a scientific conference in 2019.

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.

The company is currently finalizing a Phase 3 clinical trial protocol and will approach regulators in Europe and the U.S. to receive feedback when that is completed, which we anticipate being in early 2019. In addition, the company is pursuing various means by which to fund the Phase 3 program, which includes active business development discussions.

Conclusion

While disappointed that the second administration of topsalysin did not show any meaningful clinical benefit, we are still encouraged by the clinical response rate seen from a single administration of topsalysin. We believe a treatment for localized clinically significant prostate cancer with few side effects that could delay or even help avoid the more invasive procedures would be a welcome addition to the treatment options for those patients. We look forward to hearing additional details regarding the Phase 3 clinical trial, as well as the presentation of the full data set from the Phase 2b study in 2019. Our valuation remains $8 per share.

PROJECTED FINANCIALS

Sophiris Bio, Inc.	2017 A	Q1 A	Q2 A	Q3 A	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	$1.8	$3.5	$12.2	$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)	($3.0)	($4.7)	($16.9)	($19.0)	($19.5)
Operating Margin	-	-	-	-	-			
Non-Operating Expenses (Net)	$3.3	$1.2	($1.4)	$0.1	($0.2)	($0.3)	($0.5)	($0.5)
Pre-Tax Income	($8.6)	($3.3)	($6.1)	($2.9)	($4.9)	($17.2)	($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)**	**($2.9)**	**($4.9)**	**($17.2)**	**($19.5)**	**($20.0)**
Net Margin	-	-	-	-	-			
Reported EPS	**($0.29)**	**($0.11)**	**($0.20)**	**($0.10)**	**($0.16)**	**($0.57)**	**($0.49)**	**($0.44)**
YOY Growth	-	-	-	-	-			
Basic Shares Outstanding	30.1	30.1	30.1	30.1	30.1	30.1	40.0	45.0

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

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