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Sophiris Bio Inc. (SPHS-NASDAQ)

SPHS: Data from Second Administration of Topsalysin in Phase 2b Trial Anticipated Before End of 2018…

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 (11/20/18)	$1.95
Valuation	**$8.00**

OUTLOOK

Sophiris Bio Inc. (SPHS) is currently conducting a Phase 2b clinical trial of its lead asset, topsalysin (PRX302), in patients with localized clinically significant prostate cancer. Earlier in the year, the company announced that 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, thus approximately two-thirds of patients (25/37; 68%) demonstrated a partial or clinical response to a single administration of topsalysin.

The trial included an option for a second administration of topsalysin in patients with a partial clinical response where some clinically-significant lesion remained when assessed by biopsy. We anticipate data the patients who received a second administration of topsalysin before the end of 2018.

SUMMARY DATA

52-Week High	**$3.83**
52-Week Low	**$1.81**
One-Year Return (%)	**-4.64**
Beta	**1.85**
Average Daily Volume (sh)	**209,184**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$59**
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 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

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

Earlier in 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. 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. 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.

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.

The trial included the option to receive a second administration of topsalysin in patients who had a partial response but still had a clinically significant lesion. We anticipate data from the patients that received a second administration of topsalysin before the end of 2018.

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, however the cause of death was deemed unlikely related to the study drug or the procedure. 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.

Planning for Phase 3 Program

The company is currently planning to meet with the FDA and EMA in the first half of 2019 in order to receive feedback regarding a Phase 3 program for topsalysin in localized clinically significant prostate cancer. We believe the data collected thus far for a single administration of topsalysin supports moving the program into a Phase 3 trail. Whether the Phase 3 program will include a second administration of topsalysin will be determined following the receipt of the six-month biopsy data from patients that received a second administration and feedback from the regulatory agencies.

Financial Update

On November 13, 2018, Sophiris announced financial results for the third quarter of 2018. As expected, the company did not report any revenues. For the third quarter of 2018, Sophiris reported a net loss of $2.9 million, or

$0.10 per share, compared to a net loss of $2.7 million, or $0.09 per share, for the third quarter of 2017. Research and development expenses were $1.8 million for the third quarter of 2018 compared to $1.6 million for the third quarter of 2017. The increase in R&D expenses was primarily due to increased manufacturing costs for topsalysin partially offset by a decrease in clinical costs associated with the Phase 2b clinical trial. G&A expenses were $1.2 million for the third quarter of 2018 compared to $1.7 million for the third quarter of 2017. The decrease was primarily due to decreased marketing research activities.

As of September 30, 2018, Sophiris had approximately $14.5 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, however the company will require significant additional funding for the Phase 3 topsalysin program. As of November 8, 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. Our current valuation is $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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