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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com
scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

Achieve Life Sciences, Inc. (ACHV - NASDAQ)

1Q:19 Financial & Operational Update

Based on our DCF model and a 15% discount rate, ACHV is valued at approximately $6.00 per share. Our model applies a 15% probability of eventual cytisinicline sales based on historical Phase II trial success ratios. Our valuation includes geographic contributions from the United States only.

Current Price (5/16/2019)	$3.83
Valuation	**$6.00**

OUTLOOK

Achieve Life Sciences is developing cytisinicline for use as a smoking cessation treatment for approval and commercialization in the United States and RoW. The candidate is currently in a Ph2b optimization clinical trial which is expected to read out in mid-2019.

Two Ph3 studies are planned in up to 2,300 patients with the first starting in late 2019 and the second in first half 2020. The trials will compare cytisinicline with placebo combined with counseling. The primary endpoint is abstinence at two months with follow-up to six months.

Current products on the market have only limited effectiveness and come with unpleasant side effects including nausea, vivid dreams, insomnia and GI issues. Cytisinicline may fill a void in the prescription and NRT market by reducing nicotine cravings, the severity of withdrawal and the reward associated with smoking along with fewer side effects and shorter treatment duration. There are almost 40 million smokers in the US and over 1 billion globally, providing a substantial population demanding an improved smoking cessation product.

ACHV holds sufficient capital to complete the Ph2b but will require additional capital to complete Ph3 studies. Based on our assessment of market penetration, we maintain a target price of $6.00 per share.

SUMMARY DATA

52-Week High	**14.31**
52-Week Low	**1.04**
One-Year Return (%)	**-66.7**
Beta	**3.10**
Average Daily Volume (sh)	**1,763,626**
Shares Outstanding (mil)	**6.9**
Market Capitalization ($mil)	**26.4**
Short Interest Ratio (days)	**1.33**
Institutional Ownership (%)	**28.4**
Insider Ownership (%)	**5.0**
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	**N/A**
P/E using 2019 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2019	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2020					$0.0 E
2021					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$2.43 A	-$1.82 A	-$0.71 A	-$0.55 A	-$3.61 A
2019	-$0.88 A	-$0.33 E	-$0.18 E	-$0.20 E	-$1.20 E
2020					-$1.16 E
2021					-$0.81 E

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WHAT'S NEW

First Quarter 2019 Operational and Financial Results

Achieve Life Sciences, Inc. (NASDAQ: ACHV) released its first quarter results for 2019 and filed the companion 10-Q on May 15, 2019. An investor conference call was held following the release to discuss recent achievements and financial results. No revenues were reported for the development stage company and operational expenses totaled $5.9 million producing a net loss of ($0.88) per share. Since our previous update two months ago, the company announced the end of the ORCA-1 trial which is expected to produce topline results mid-year.

Net loss for 1Q:19 was ($5.9) million or ($0.88) per share on a weighted average share count of 6.72 million. This was comprised of operational costs of $5.9 million, and a small amount of interest and other expenses.

Total research and development expense of $5.9 million rose 238% from the $1.2 million spent in 1Q:18. The increase was attributable to spending on the ORCA-1 trial, which was launched in October 2018 and was fully enrolled the first quarter. General and administrative expenses were $1.9 million in the three month period, rising from $1.8 million during the prior year period. The 4% rise came from greater share based compensation and higher employee expenses.

Cash burn was ($4.9) million in 1Q:19, compared to ($2.2) million in 1Q:18 due to trial activity related to completing enrollment of the ORCA-1 trial and other trial work. Cash and equivalents and short-term investments as of March 31, 2019 were $9.7 million, about $5 million less than year-end levels. As of May 15, 2019, 6.87 million shares are outstanding.

Results from PK/PD Study

On February 22nd, Achieve released a summary of final data for its Phase I/II multi-dose, pharmacokinetic and pharmacodynamics (PK/PD) clinical study of cytisinicline in smokers.

The results of the 26-patient trial demonstrated a dose dependent response with abstinence levels of 39% in the 1.5 mg group and 54% in the 3.0 mg group. Following the 25-day course of therapy, subjects had an 80% reduction in cigarettes smoked, an 82% reduction in CO expiration and a 46% quit rate. The trial demonstrated high quit rates despite no commitment to quit by participants and minimal behavioral support.

ORCA-1 Trial

Full enrollment in the Ongoing Research of Cytisinicline for Addiction (ORCA)-1 trial was reached in February 2019. 254 subjects were enrolled in the Phase IIb study which is evaluating a 1.5 mg and 3.0 mg dose in the 25-day treatment for nicotine addiction with cytisinicline. In late April the company announced that the last subject had his last visit. Topline efficacy and safety data are expected to be available in mid-2019. Results from the trial will be used to refine the design of the upcoming Phase III studies.

MTD Study

A maximum tolerated dose (MTD) study was launched in March to determine stopping criteria and dose-limiting events for cytisinicline. Starting dose was 6 mg which was increased in 3 mg increments for a total of 6 dose increments. The highest daily dose to date used in the trials has been 21 mg with no evidence of dose limiting toxicity. The Data Safety Monitoring Committee (DSMC) recommended that the protocol be amended to examine higher doses, up to 30 mg, which will require ethics committee approval. The lack of evidence of serious side effects provides additional evidence of safety for cytisinicline.

Phase III Trial

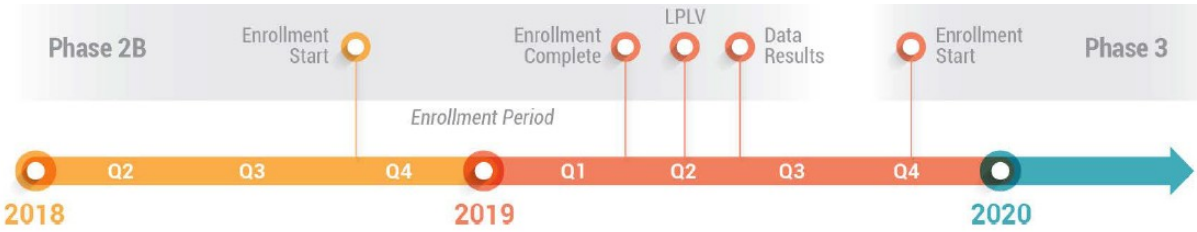
Achieve is on track to start its Phase III trial in the second half of 2019. There are trial design issues that are being finalized with the FDA and will be guided by the results of the ORCA-1 and other trials being conducted. The areas to be confirmed include trial execution, statistical powering and optimal dosing. It is this last component which is most interesting given the dose response observed in the PK/PD study. To explore dose efficacy more thoroughly, a MTD study was launched in March. Competitor varenicline was dose limited by the off-target effects (most commonly nausea) that we discussed in our initiation, a profile that cytisinicline may not have. If there is a positive

dose response relationship at higher levels of cytisinicline, and the side effect profile remains favorable, higher efficacy could be the outcome.

Key Events

- Last patient enrolled in Phase IIb – February 2019
- Repeat dose final study final results release – February 2019+
- Launch of MTD study – March 2019
- Second and final DSMC review of ORCA-1 – April 2019
- Last patient, last visit Phase ORCA-1 – April 2019
- Top line results from ORCA-1 trial – mid-2019
- Launch 800 person Phase III trial – 4Q:19
- Launch 1,500 person Phase III trial – first half 2020
- Complete 800 person Phase II trial 4Q:20
- Complete 1,500 person Phase III trial – year end 2021
- Submit NDA to FDA – 2022
- FDA response and launch of cytisinicline - 2023

Exhibit I – Planned Development Program and Milestones



Activity	Anticipated Timing
First patient enrolled P2b	Q4 2018 ✓
Last patient enrolled P2b	Q1 2019 ✓
Repeat Dose Study Final Study Results	Q1 2019 ✓
Maximum Tolerated Dose (MTD) Study Initiation	Q1 2019 ✓
Top line results P2b	Q2 2019
MTD Study Results	Q3 2019
Phase 3 Trial Initiating	Q4 2019

ORCA Ongoing Research of Cytisinicline for Addiction

Summary

We believe that the long historical use of cytisinicline provides confidence that the upcoming Phase III trials will be successful and will provide the necessary data to obtain FDA approval, presenting a relatively low risk pursuit for a new chemical entity in the United States. Achieve holds sufficient capital on its balance sheet to complete the Phase IIb trial and other ongoing studies. However, additional capital will be needed to launch the two Phase III studies which are anticipated to begin before year end. We anticipate a capital raise after successful data from the ORCA-1 trial is released. There is also the potential to work with a partner who has a primary care salesforce and other infrastructure already in place. Suitors could include Pfizer, which will need a replacement for Chantix, GSK, which has both Zyban and NRT offerings, and even Perrigo, Johnson & Johnson and Amarin who all have primary care salesforces in place and would benefit from layering on a complementary product. If Phase III trials are able to show materially improved success over what varenicline has achieved, we anticipate even higher sales than what we forecast in our model and potentially more interest from big pharma. Based on our conservative estimates, shares of ACHV are undervalued relative to their potential. We maintain our target price of $6.00.

PROJECTED FINANCIALS

Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2018 A	Q1 A	Q2 E	Q3 E	Q4 E	2019 E	2020 E	2021 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
	-					-	-	-
R&D	$5.9	$4.1	$2.2	$1.6	$2.8	$10.7	$26.0	$21.0
G&A	$6.9	$1.9	$1.8	$1.8	$1.8	$7.3	$7.6	$8.0
Other expenses								
Operating Income	($12.8)	($5.9)	($4.0)	($3.4)	($4.6)	($17.9)	($33.6)	($29.0)
Operating Margin	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*
Interest Income	$0.2	$0.0	$0.0	$0.1	$0.1	$0.2	$0.0	$0.0
Total Other Income	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($12.7)	($5.9)	($4.0)	($3.3)	($4.5)	($17.7)	($33.6)	($29.0)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*$0.0*
Net Income	($12.7)	($5.9)	($4.0)	($3.3)	($4.5)	($17.7)	($33.6)	($29.0)
Reported EPS	**($3.61)**	**($0.88)**	**($0.33)**	**($0.18)**	**($0.20)**	**($1.20)**	**($1.16)**	**($0.81)**
YOY Growth								
Shares Outstanding	3.5	6.7	12.0	18.0	22.0	14.7	29.0	36.0

Source: Company Filing // Zacks Investment Research, Inc. Estir

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HISTORICAL STOCK PRICE

Achieve Life Sciences, Inc. – Stock Price Chart[1]



[1] Source: Price chart courtesy of barchart.com

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