Zacks Small-Cap Research

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Achieve Life Sciences, Inc. (ACHV - NASDAQ)

After Capital Raise Ready for Phase III

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 (11/6/2019)	$1.05
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 recently completed a Ph2b optimization clinical trial which provided detailed data in September 2019.

Two Ph3 studies are planned with the first starting in 2020 and the second based on availability of additional funding. The trials will compare cytisinicline with placebo combined with counseling. The primary endpoint is abstinence at 6 and 12 weeks.

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 launch Ph3 studies. Based on our assessment of market penetration, we maintain a target price of $6.00 per share.

SUMMARY DATA

52-Week High	**4.63**
52-Week Low	**0.99**
One-Year Return (%)	**-51.4**
Beta	**1.4**
Average Daily Volume (sh)	**106,352**
Shares Outstanding (mil)	**8.4**
Market Capitalization ($mil)	**8.8**
Short Interest Ratio (days)	**1.94**
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 2019 Estimate	**N/A**
P/E using 2020 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 A	$0.0 A	$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	-$0.50 A	-$0.45 A	-$0.20 E	-$1.61 E
2020					-$1.16 E
2021					-$0.81 E

WHAT'S NEW

Third Quarter 2019 Operational and Financial Results

Achieve Life Sciences, Inc. (NASDAQ: ACHV) released its third quarter results for 2019 and filed the companion 10-Q on November 6, 2019. An S-1 was simultaneously issued targeting a $10 million raise in order to partially fund the upcoming Phase III trials. Following the releases, an investor conference call was held to discuss financial results and recent achievements. No revenues were reported for the development stage company and operational expenses totaled $3.7 million producing a net loss of ($0.45) per share. Highlights for the third quarter include the extension of a collaboration with the National Institute of Health (NIH), an investor day which delved into the detail of the ORCA-1 trial and the completion of the Maximum Tolerated Dose (MTD) study. In September and in October the company presented cytisinicline data at two Society for Research on Nicotine & Tobacco (SRNT) conferences.

Research and development expense of $1.8 million rose 18% from the $1.5 million spent in 3Q:18. The increase was attributable to spending on follow up data analysis for the ORCA-1 trial, which was launched in October 2018 and was completed in June 2019. General and administrative expenses were $1.9 million in the three month period, rising from $1.8 million the year prior period. The 8% rise was attributable to initiation of market research activities related to cytisinicline and smoking cessation. Net loss for 3Q:19 was ($3.7) million or ($0.45) per share on a weighted average share count of 8.10 million.

Cash burn was ($3.1) million in 3Q:19, compared to ($3.0) million in 3Q:18 due to a greater net loss partially offset by stock based compensation and a build in accrued compensation. Cash and equivalents and short-term investments as of September 30, 2019 were $7.4 million, a sequential increase of $3.1 million. As of November 6, 2019, 8.35 million shares are outstanding.

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 completed his last visit. Topline from the dose selection study was reported on June 11, with a primary endpoint of a reduction in daily smoking at the end of treatment. Subjects enrolled in the trial were considered difficult to treat as they had been long term smokers, and averaged four and a half previous quit attempts. Smoking abstinence was measured at week four, which coincided with the end of the trial. Additional measurements from weeks five through eight were also performed. Number of cigarettes smoked were self-reported and carbon monoxide (CO) testing was also conducted to verify exposure. Study results demonstrated a relationship between the use of cytisinicline and number of cigarettes smoked as well as a decline in expired CO as compared to placebo. Safety results were favorable, with no serious adverse events reported. Despite the dose selection objective of the trial, the statistical significance of the quit rate at four weeks claimed an impressive p-value of less than 0.0001 for the highest 3 mg t.i.d. rate.

Exhibit I – ORCA-1 Data Summary[1]

	3 mg tid	Placebo	p-value	3 mg tid	Placebo	p-value
	At 4 weeks			Weeks 5 - 8		
Quit rate	54%	16%	< 0.0001	30%	8%	0.005
Odds Ratio	6.3x					
	Reduction Across All Arms					
Smoking Reduction	74 - 80%	62%	< 0.05			
Expired CO	71 - 80%	38%	< 0.05			

Safety analysis observed no adverse events in greater than 10% of the subjects and no serious adverse events. One of the shortcomings of competing therapies has been low adherence to therapy due to unpleasant side effects. In the ORCA-1 trial, adherence was 98%, suggesting treatment was very tolerable. The most common adverse events for the 3 mg t.i.d. dose (vs placebo) were abnormal dreams, insomnia, and constipation (each 6% vs 2%), upper respiratory tract infections (6% vs 14%), and nausea (6% vs 10%). During the 2Q:19 conference call,

[1] Source: Zacks' summary of Achieve Life Sciences Data

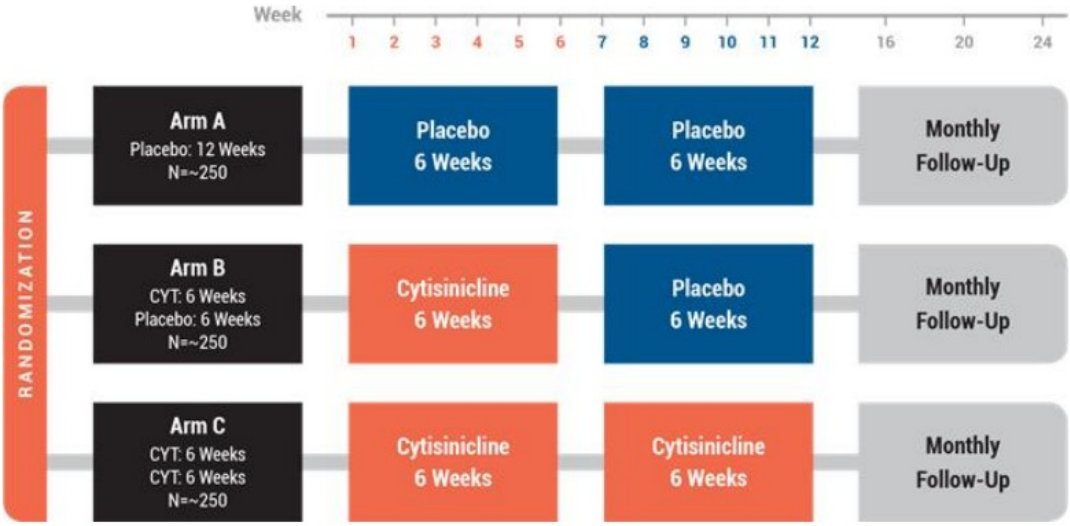
management shared some of the commentary from subjects in the study. Patients were grateful for the treatment and were impressed by its short duration.

On September 20th Achieve held an investor day in New York with several key opinion leaders and discussed the smoking cessation environment and cytisinicline's role here. We published an article on September 25th discussing the details of the informational meeting. The investor day highlighted the potential for cytisinicline, which we see as a de-risked asset with potential annual sales over $1 billion.

Phase III Trial

Following the successful Phase IIb ORCA-1 trial, Achieve is now finalizing details for the two Phase III trials that are expected to start next year. Dosing is anticipated to be 3.0 mg, three times daily in a six week and twelve week treatment period. The primary endpoint for the trial will be smoking abstinence during the last four weeks of the treatment period and the secondary endpoint will be abstinence at 24 weeks. Before year end, Achieve will meet with the FDA to finalize trial details to ensure modifications to the protocols meet the agency's approval. The discussions will revolve around using the higher 3.0 mg t.i.d. dose, the simplification of the dosing and the increased treatment duration to drive more durable efficacy.

Exhibit II – Phase III Trial Design[2]



During the conference call, Achieve raised the possibility of conducting a study measuring the effectiveness of cytisinicline for e-cigarette cessation. The study would be funded using non-dilutive capital, perhaps from a grant or other government source. E-cigarettes have experienced a growing presence, especially in the younger population. In recent months, many of the risks associated with the use of e-cigarettes have become apparent, highlighting the need to treat nicotine addiction in this population. At this time it is unclear how the trial may be designed or the timeline for its completion.

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 study was completed after reaching 30 mg where there was no evidence of dose limiting toxicity. The lack of evidence of serious side effects provides additional evidence of safety for cytisinicline.

[2] Source: Achieve Life Sciences S-1 Filed November 6, 2019.

Key Events

- Last patient enrolled in Phase IIb – 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 – June 2019
- Presentation of data at SRNT-E and SRNT-O meetings – September / October 2019
- Final Study Results for MTD Study – 3Q:19
- FDA End of Phase II Meeting – 4Q:19
- Launch Phase III trial – 1H:20
- Last Patient Visit Phase III trial – 2H:20
- Top Line Data Phase III trial – 1H:21

Summary

We believe that the long historical use of cytisinicline provides evidence of safety and efficacy which we anticipate will be confirmed in the upcoming Phase III trials. These registrational efforts will generate the necessary data to obtain FDA approval, presenting a relatively low risk pursuit for a new chemical entity in the United States. Achieve has completed its Phase IIb trial and maximum tolerated dose investigation. However, additional capital will be needed prior to launching the two Phase III studies. We anticipate funding for the trial will come from an equity raise and contributions from a larger collaborator. Partners with a primary care salesforce and other infrastructure already in place are most attractive. 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. The next milestones on the horizon are a meeting with the FDA to finalize protocol and a capital raise to fund Phase III. Based on our conservative estimates, shares of ACHV are undervalued relative to their potential. We maintain our target price of $6.00.

PROJECTED FINANCIALS

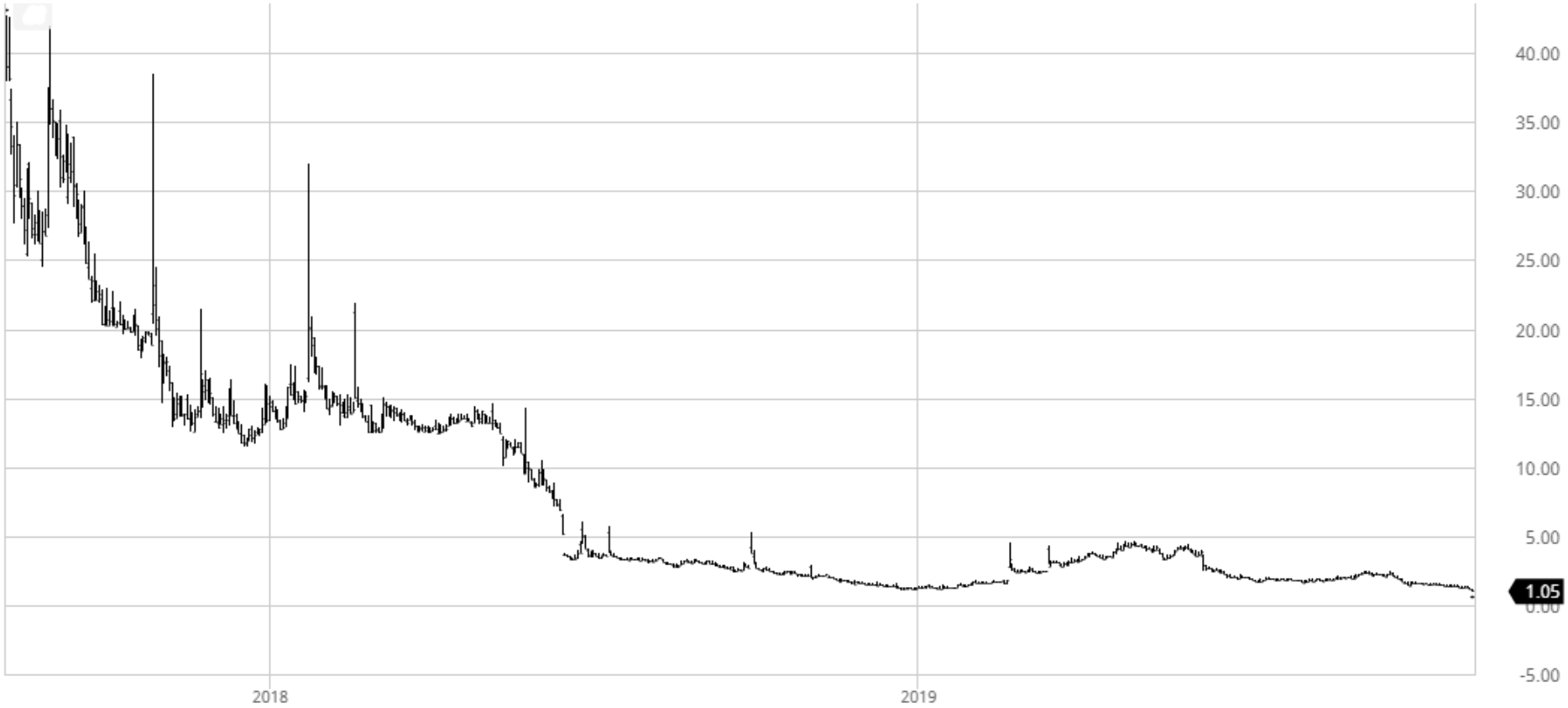
Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2018 A	Q1 A	Q2 A	Q3 A	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	$2.0	$1.8	$1.6	$9.5	$26.0	$21.0
G&A	$6.9	$1.9	$1.6	$1.9	$1.7	$7.1	$7.6	$8.0
Operating Income	($12.8)	($5.9)	($3.7)	($3.7)	($3.3)	($16.6)	($33.6)	($29.0)
Interest Income	$0.2	$0.0	$0.0	$0.0	$0.1	$0.1	$0.0	$0.0
Total Other Income	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.1	$0.0	$0.0
Pre-Tax Income	($12.7)	($5.9)	($3.6)	($3.7)	($3.2)	($16.4)	($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)	($3.6)	($3.7)	($3.2)	($16.4)	($33.6)	($29.0)
Reported EPS	**($3.61)**	**($0.88)**	**($0.50)**	**($0.45)**	**($0.15)**	**($1.49)**	**($1.16)**	**($0.81)**
YOY Growth								
Shares Outstanding	3.5	6.7	7.2	8.1	22.0	11.0	29.0	36.0

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

HISTORICAL STOCK PRICE

Achieve Life Sciences, Inc. – Stock Price Chart[3]



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

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