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Achieve Life Sciences, Inc. (ACHV - NASDAQ)

Extended Treatment May Improve Quit Rates

Based on our DCF model and a 15% discount rate, ACHV is valued at approximately $3.00 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 (3/13/2020)	$0.31
Valuation	**$3.00**

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 raised funds to launch the first of its Phase III studies but will require additional capital to complete the second. We anticipate a 2024 commercialization of cytisinicline.

SUMMARY DATA

52-Week High	**4.63**
52-Week Low	**0.30**
One-Year Return (%)	**-87.5**
Beta	**1.5**
Average Daily Volume (sh)	**2,581,522**
Shares Outstanding (mil)	**31.4**
Market Capitalization ($mil)	**9.58**
Short Interest Ratio (days)	**0.11**
Institutional Ownership (%)	**25.6**
Insider Ownership (%)	**1.7**
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 2020 Estimate	**N/A**
P/E using 2021 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 A	$0.0 A
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	-$0.30 A	-$1.99 A
2020					-$0.93 E
2021					-$0.81 E

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WHAT'S NEW

Fourth Quarter and Full Year 2019 Review

Achieve Life Sciences, Inc. (NASDAQ: ACHV) reported fourth quarter and full year results in a press release and conference call held on March 13th 2020. The company concurrently filed its 2019 10-K with the SEC. 2019 highlights include company presentation at three SRNT conferences, completion of the Phase IIb ORCA-1 trial, conclusion of the MTD study, the first investor day, design of a Phase III trial and an end of year capital raise to fund the study. Most importantly, data from the Phase IIb trial were supportive of safety and efficacy, demonstrating a 54% quit rate at the end of treatment.

Cytisinicline has several toxicity studies underway, including the National Institute of Health (NIH) reproductive study which will be conducted in rabbits. The other two evaluations include a nine-month canine study and a carcinogenicity study. This research will satisfy the FDA's requirement for assessments to be performed in two different species. Prior to starting the Phase III, a 13-week interim report from the canine study and the final protocol for the trial are required. We do not anticipate any concerns to arise from the toxicity studies given the long history of cytisinicline use. However, if concerns do arise, we feel that this will result in increased monitoring rather than any delay to the trial. We also point to the maximum tolerated dose (MTD) study which increased doses in humans up to 30 mg with no evidence of dose limiting toxicity. While the animal toxicity study will examine lower doses than those used in the MTD study, they will be examined over a longer period.

In December, the company updated investors on the outcome from the end of Phase II meeting with the FDA. The FDA provided guidance on Phase III protocols and agreed with the simplified dosing schedule that employs a 3.0 mg dose three times daily over a six and 12 week course of treatment. The FDA also agreed with the use of a single 3.0 mg tablet to replace the 1.5 mg tablet used in previous trials.

Fourth Quarter and Full Year 2019 Financial Performance

Research and development expenses totaled $9.7 million in 2019, up 65% from prior year levels of $5.9 million. The higher levels of R&D are attributable to the Phase IIb ORCA-1 trial and subsequent analysis that was ongoing during the year. General and administrative expenses for the year were flat at $6.9 million. Net loss for 2019 was ($16.4) million or ($1.99) per share on a weighted average share count of 8.2 million. Fourth quarter 2019 expenses were down over the prior year as the ORCA-1 trial was underway in the 4Q:18 period but had been completed prior to 4Q:19. Net loss for 4Q:19 was ($3.2) million.

Cash burn was ($15.3) million for 2019 compared to ($10.7) million in 2018 due to a greater net loss partially offset by great stock based compensation and a build in accounts payable and prepaid expenses. Cash and equivalents and short-term investments as of December 31, 2019 were $16.7 million, an increase from prior year levels of $14.7 million. $17.3 million in cash flows were added from financing during 2019. In December 2019, Achieve raised $13.8 million in an underwritten public offering which along with other minor adjustments brings the share balance to 31.35 million shares outstanding as of March 13, 2020.

Vaping Trial

In February, Achieve executed an agreement with FreeMind Group to identify and secure non-dilutive capital from government and private sources to fund a Phase II study on the efficacy of using cytisinicline for smoking cessation in vaping and e-cigarette users. Data cited by the company from the Annals of Internal Medicine identified nearly 11 million users of vaping products and e-cigarettes. The Phase II trial is expected to be a double blind randomized trial similar in structure to the Phase III the company will launch later this year. It will measure vaping abstinence for six and 12 weeks using carbon monoxide and serum cotinine levels to determine the primary endpoint. The timing of the trial is independent of the Phase III and is dependent on securing the non-dilutive financing.

Presentation of Data at SRNT, New Orleans

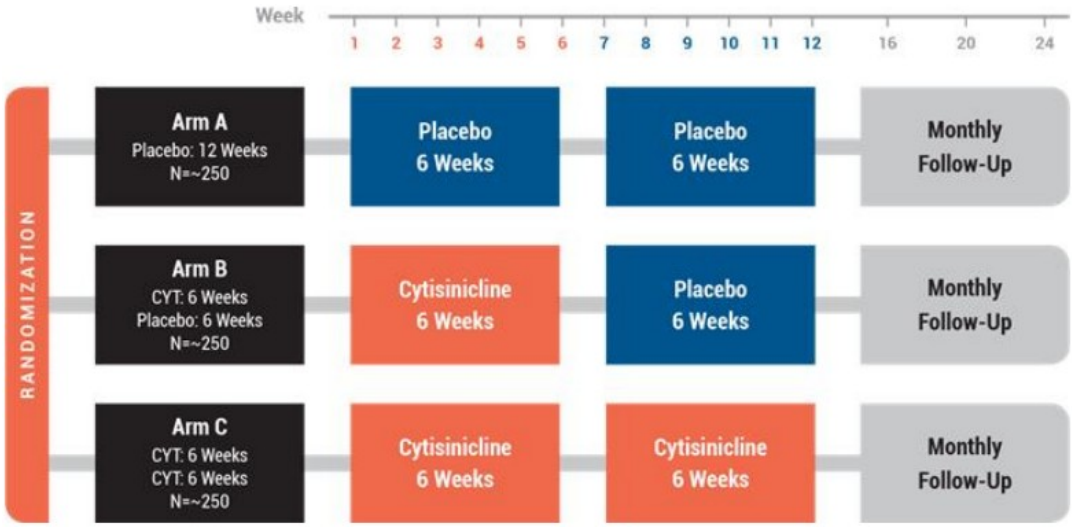
On March 12th, Dr. Mitchell Nides, principal investigator for the ORCA-1 trial, presented an analysis of data for the study. The presentation reiterated much of the information provided in previous releases, but also provided additional detail regarding benefit of cytisinicline across varied baseline characteristics. Further analysis did not find any differences in benefit from cytisinicline treatment based on race, gender, age or body mass index. Neither did

smoking history, nor type of previous cessation product affect the utility of the drug. No clinical site differences were observed and there was no treatment difference between slow and fast nicotine metabolizers.

Phase III Trial

The interim chronic toxicology report is expected to be submitted to the FDA in April, cytisinicline tablets are ready for disbursement, the contract research organization has been selected and clinical sites are being identified. We anticipate a mid-year start for the first of two Phase III cytisinicline studies. As we have previously reported, 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. Achieve met with the FDA in December to finalize trial details to ensure modifications to the protocols meet the agency's approval. The discussions centered on 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[1]



RAOURA Study

While we felt there was a chance that the data from the New Zealand RAUORA[2] study might be presented at the New Orleans Society for Research on Nicotine & Tobacco (SRNT) meeting last week, it appears that it is more likely to be presented at the fall SRNT conference. This head to head trial comparing cytisinicline and varenicline[3] may demonstrate superior safety and efficacy for Achieve's in-development product. The study has enrolled 2,140 Māori and their extended family in a randomized, non-inferiority trial. Enrollment has completed and data is likely in the process of being prepared for publication.

Capital Raise

On December 19th, Achieve closed a $13.8 million public offering issuing 12,577,504 shares of common stock and 6,256 shares of Series B preferred stock and 23,000,000 warrants. The shares issued included the exercise of the 3 million share overallotment option. Each unit of the Series B preferred stock is convertible into 1,666 shares of common stock. Each common share has one warrant attached and each unit of preferred stock has 1,666 warrants attached, all with an exercise price of $0.60 and a life of 5 years. The shares and Series B preferred stock represent an additional 23 million shares.

[1] Source: Achieve Life Sciences S-1 Filed November 6, 2019.
[2] Rauora is the Māori word for rescue
[3] Branded Chantix from Pfizer in the United States

Key Events

- 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
- Presentation of additional analyses of ORCA-1 at SRNT New Orleans – March 2020
- Complete animal toxicity study – 1Q:20
- Possible RAUORA Data Presentation at SRNT Switzerland – September 2020
- Launch Phase III trial – mid-year 2020

Summary

We believe that the long historical use of cytisinicline provides supporting 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. Additional capital has been raised which will fund the first of two Phase III studies. We anticipate that Achieve will need approximately $15 million plus general and administrative expenses to conduct the 750 subject trial. With $16.7 million on the balance sheet as of December 31, 2020, they are close to having sufficient funds to complete the effort. An additional capital raise or interest from a a larger collaborator may provide sufficient dollars to complete the trial. 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 the submission of the toxicity study to the FDA, raise of an additional amount of capital and the launch of the Phase III. Based on our conservative estimates, shares of ACHV are undervalued relative to their potential. We maintain our valuation of $3.00 per share.

PROJECTED FINANCIALS

Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2018 A	Q1 A	Q2 A	Q3 A	Q4 A	2019 A	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	$1.8	$9.7	$21.8	$21.0
G&A	$6.9	$1.9	$1.6	$1.9	$1.4	$6.9	$7.6	$8.0
Operating Income	($12.8)	($5.9)	($3.7)	($3.7)	($3.2)	($16.5)	($29.4)	($29.0)
Interest Income	$0.2	$0.0	$0.0	$0.0	$0.0	$0.0	$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)	($29.4)	($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)	($29.4)	($29.0)
Reported EPS	**($3.61)**	**($0.88)**	**($0.50)**	**($0.45)**	**($0.30)**	**($1.99)**	**($0.93)**	**($0.81)**
YOY Growth								
Shares Outstanding	3.5	6.7	7.2	8.1	10.8	8.2	31.6	36.0

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

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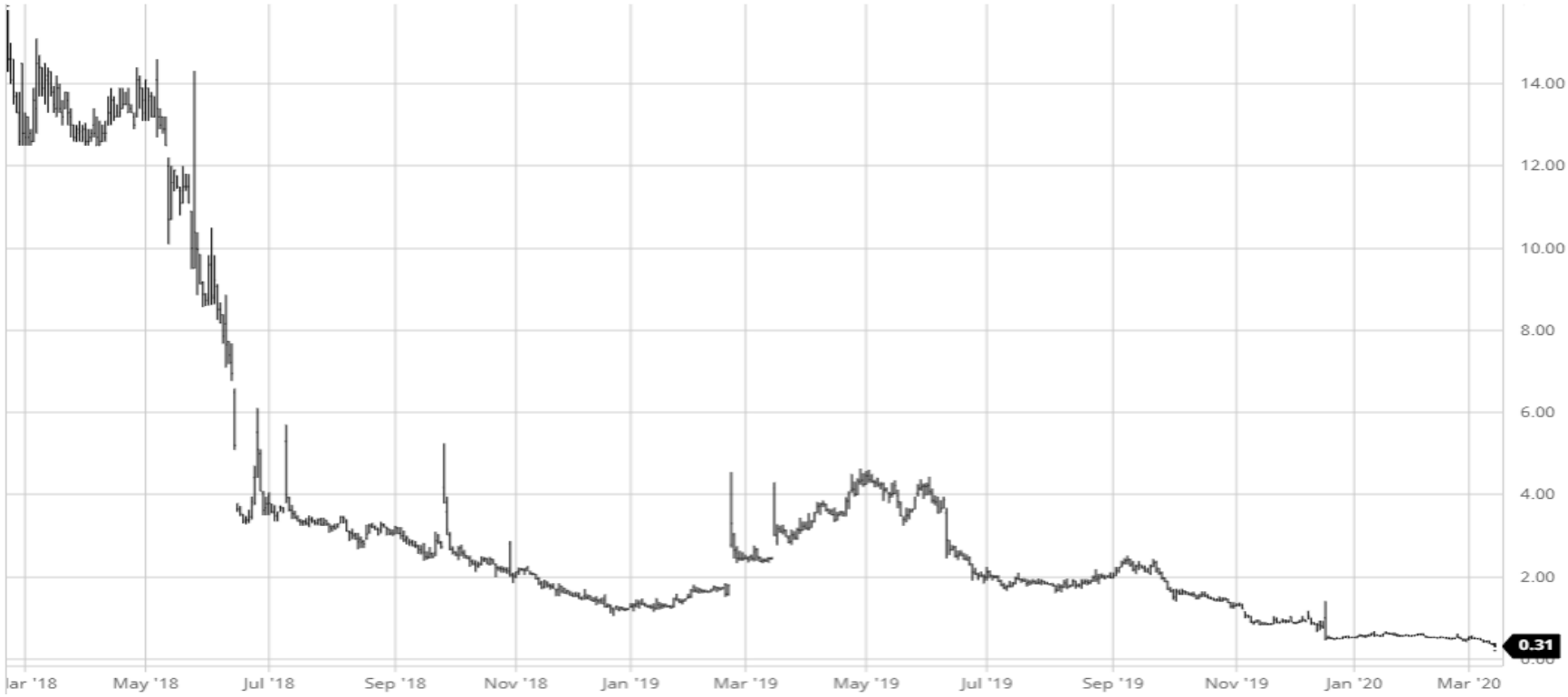
HISTORICAL STOCK PRICE

Achieve Life Sciences, Inc. – Stock Price Chart[4]



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

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