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Achieve Life Sciences, Inc. (ACHV - NASDAQ)

Phase III Ready (ORCA)-2 Go

Based on our DCF model and a 15% discount rate, ACHV is valued at approximately $2.50 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 (5/14/2020)	$0.39
Valuation	**$2.50**

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 expected to start in 2H:20 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 expects to launch the first of its Ph3 trials in 2H:20 and begin enrolling in earnest by beginning of year 2021. We anticipate a 2024 commercialization of cytisinicline.

SUMMARY DATA

52-Week High	**4.43**
52-Week Low	**0.23**
One-Year Return (%)	**-90.8**
Beta	**1.41**
Average Daily Volume (sh)	**1,031,487**
Shares Outstanding (mil)	**37.5**
Market Capitalization ($mil)	**14.6**
Short Interest Ratio (days)	**0.05**
Institutional Ownership (%)	**17.1**
Insider Ownership (%)	**1.1**
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)
2019	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2020	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2021					$0.0 E
2022					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.88 A	-$0.50 A	-$0.45 A	-$0.30 A	-$1.99 A
2020	-$0.11 A	-$0.19 E	-$0.22 E	-$0.20	-$0.73 E
2021					-$0.58 E
2022					-$0.51 E

*2019 quarterly does not sum to full year due to distorting effects of share issuance

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WHAT'S NEW

First Quarter 2020 Review

Achieve Life Sciences, Inc. (NASDAQ: ACHV) reported first quarter results in an early morning press release and conference call held on May 14th 2020. The company concurrently filed its 2019 10-Q with the SEC. While disruptions related to the coronavirus have required new safety measures, Achieve now anticipates a 2H:20 start to the first of two Phase III trials. Year to date 2020 highlights include publication of an AI study on nicotine effect, engagement of FreeMind Group to obtain funding for a vaping study, presentation at the SRNT 2020 Annual Meeting, and a small capital raise. During the conference call management announced that they have submitted all required documents to the FDA and anticipate starting the Phase III ORCA-2 trial this fall pending receipt of funding.

The upcoming Phase III trial will differ from the ORCA-1 trial in its design. First, the evaluation of a 3 mg dose three times per day will be used; second, a simplified dosing schedule will be administered, thereby avoiding the declining titration schedule employed previously and third, the extension of treatment will include both a six week and twelve week evaluation. The last modification may materially improve success rates as patients will continue treatment through the twelve week cohort when abstinence is measured.

First Quarter 2020 Financial Performance

Research and development expenses totaled $1.5 million in 1Q:20, down 62% compared to 1Q:19 due to the completion of the ORCA-1 trial last year. 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 $1.8 million, falling a modest 4% over first quarter 2019 levels. Lower travel costs were cited as the reason. Net loss for 1Q:20 was ($3.3) million or ($0.11) per share on a weighted average share count of 30.9 million.

Cash burn was ($4.5) million for the first quarter, compared with ($4.9) million in the comparable prior period. Cash and equivalents and short-term investments as of March 31, 2020 were $12.2 million, a reduction from fourth quarter levels. Following the end of the first quarter, Achieve completed a private placement and raised $1.9 million gross proceeds.

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 cytisinicline for smoking cessation in vaping and e-cigarette users. These users comprise a large group that have not been studied extensively in nicotine addiction trials. 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. Achieve has applied for a three year grant that, if awarded, will provide $5 million per year to fund the effort.

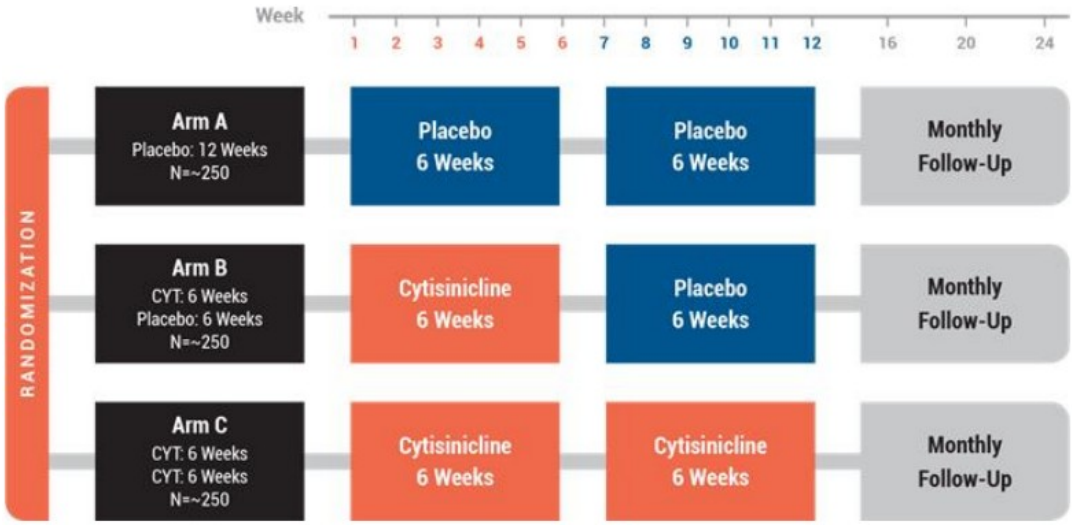
Presentation of Data at SRNT, New Orleans

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 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

All materials required to start the ORCA-2 trial were submitted to the FDA in April, cytisinicline tablets are ready for disbursement, the contract research organization has been selected and 15 clinical sites have been identified. We anticipate a second half start for the first of two Phase III cytisinicline studies. Dosing is anticipated to be 3.0 mg, three times daily in both the six week and twelve week treatment cohorts. 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 protocol modifications meet the agency's approval.

Exhibit II – Phase III Trial Design[1]



RAOURA Study

We concur with Achieve management's best guess that the data from the New Zealand RAUORA[2] study will be presented at a conference later this year. This will likely be 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 and if so will provide strong justification for commercialization. The study enrolled 2,140 Māori and their extended family in a randomized, non-inferiority trial. Enrollment is complete and data is likely in the process of being prepared for publication.

Capital Raise

In April 2020, Achieve issued 5,615,653 shares of stock in a private placement that raised gross proceeds of $1.9 million at $0.33 per share. Paulson Investment Company acted as the placement agent. The deal included 75% warrant coverage, issuing 4.2 million warrants with an exercise price of $0.362. Warrants have a five year life. An additional 505,409 broker warrants were also issued at an exercise price of $0.3795. Net proceeds after expenses were $1.6 million.

Achieve also updated its agreement with Lincoln Park Capital, obtaining the right to sell $11 million of common stock shares. The duration of the agreement was extended to 54 months stretching the original term until March 2022. No shares have been sold through this arrangement in 2020.

Valuation

We update our valuation to reflect our estimated delay of the trial start date and the ultimate commercialization date for cytisinicline by several months. Our change in valuation is also impacted by current and near-term anticipated share balance. We move our target to $2.50 per share.

Key Events

- Presentation of additional analyses of ORCA-1 at SRNT New Orleans – March 2020
- Complete animal toxicity study – 2Q:20
- Possible RAUORA Data Presentation at SRNT Switzerland – September 2020
- Second chronic toxicology study submission to FDA – 4Q:20
- Launch Phase III trial – 2H:20

[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

Summary

We believe that the historical use of cytisinicline lends support to its 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 and management has guided toward a second half 2020 start to the ORCA-2 trial pending funding. An additional capital raise or interest from a larger collaborator may provide sufficient dollars to complete the effort. 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 raise of additional capital and the launch of the Phase III. Based on our conservative estimates, shares of ACHV are undervalued relative to their potential. Our valuation of Achieve is $2.50 per share.

PROJECTED FINANCIALS

Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2019 A	Q1 A	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
	-					-	-	-
R&D	$9.7	$1.5	$5.0	$7.5	$7.5	$21.5	$21.0	$21.5
G&A	$6.9	$1.8	$1.9	$1.9	$1.9	$7.5	$8.0	$8.3
Operating Income	($16.5)	($3.4)	($6.9)	($9.4)	($9.4)	($29.1)	($29.0)	($29.8)
Interest Income	$0.0					$0.0	$0.0	$0.0
Total Other Income	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($16.4)	($3.3)	($6.9)	($9.4)	($9.4)	($29.0)	($29.0)	($29.8)
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	($16.4)	($3.3)	($6.9)	($9.4)	($9.4)	($29.0)	($29.0)	($29.8)
Reported EPS	**($1.99)**	**($0.11)**	**($0.19)**	**($0.22)**	**($0.20)**	**($0.73)**	**($0.58)**	**($0.51)**
YOY Growth								
Shares Outstanding	8.2	30.9	37.0	43.0	48.0	39.7	50.0	58.0

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: Zacks Research System

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