Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

January 3, 2020
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)

Toxicology Study to Complete in Q1

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 (1/2/2020)	$0.52
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 complete the first of its Phase III studies but will require additional capital to launch the second. We anticipate a 2024 launch of cytisinicline.

SUMMARY DATA

52-Week High	**4.63**
52-Week Low	**0.46**
One-Year Return (%)	**-60.3**
Beta	**1.1**
Average Daily Volume (sh)	**1,178,655**
Shares Outstanding (mil)	**31.4**
Market Capitalization ($mil)	**16.3**
Short Interest Ratio (days)	**3.6**
Institutional Ownership (%)	**28.4**
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 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	-$0.25 E	-$1.87 E
2020					-$1.04 E
2021					-$0.73 E

© Copyright 2020, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

December Update

On December 9th, Achieve Life Sciences, Inc. (NASDAQ: ACHV) 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.

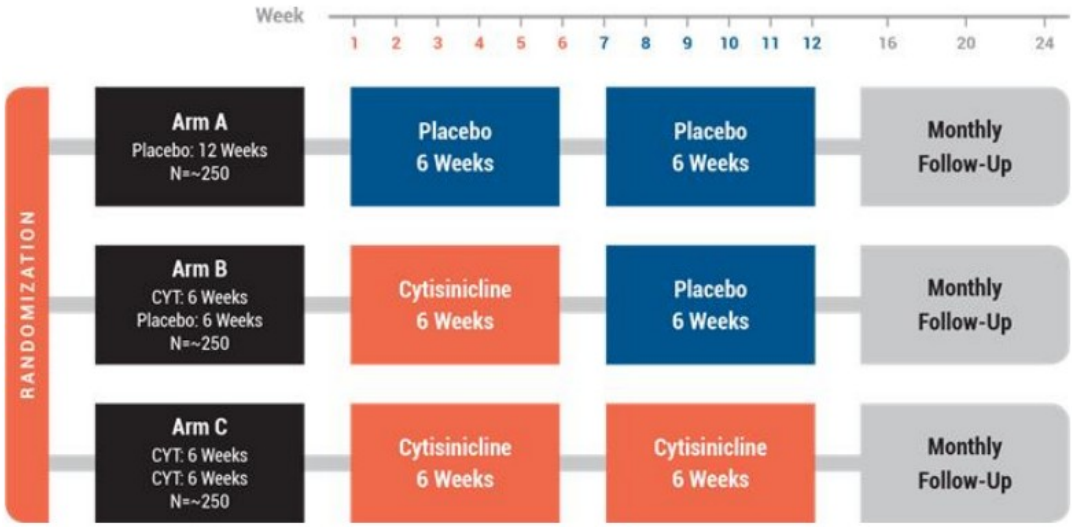
The FDA requested a second chronic toxicology study due to the change in protocol from what was used in the Phase II. The results of this animal study are expected to be submitted to the FDA in 1Q:20. We do not anticipate any issues to arise from the toxicology study given the long history of use for cytisinicline. 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.

With a capital raise now under their belt, we see Achieve launching the first of two Phase III studies in the second quarter of 2020.

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 in 2020. 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 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. Following the meeting, the FDA requested that an animal toxicity study be performed to evaluate the risks in the new dosing regimen. Data from the toxicity study must be submitted to the FDA prior to the start of the Phase III. We anticipate submission will take place in 1Q:20 and the Phase III will begin in 2Q:20.

Exhibit II – Phase III Trial Design[1]



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

RAOURA Study

An important catalyst that may take place in the next few months is the presentation of data from the RAUORA[2] study at the Society for Research on Nicotine & Tobacco (SRNT) meeting in mid-March 2020. This head to head trial comparing cytisinicline and varenicline[3] may demonstrate superior safety and efficacy for Achieve's in-development product. The study plans to enroll 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. 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.

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
- Complete animal toxicity study – 1Q:20
- Possible RAUORA Data Presentation at SRNT – March 2020
- Launch Phase III trial – 2Q:20
- Last Patient Visit Phase III trial – 2H:20
- Top Line Data Phase III trial – 1H:21

Valuation

Achieve issued the equivalent of 23 million new shares and a similar number of warrants in the most recent capital raise. We adjust our target price to reflect the incresed share count and outsanding warrants with exercise prices at $0.60. We also shift back the start of the Phase III trial by one quarter to allow for the animal toxicity study to complete. It is likely that the the second Phase III trial will be delayed compared to our initial estimates and we push back our NDA submission and target for ultimate commercialization by two quarters. These adjustments reduce our price target to $3.00.

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. 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. To reflect the impact of dilution from the issuance of new shares and delay in launching the Phase III, we reduce our target price to $3.00.

[2] Rauora is the Māori word for rescue
[3] Branded Chantix from Pfizer in the United States

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)**	**($0.25)**	**($1.87)**	**($1.04)**	**($0.73)**
YOY Growth								
Shares Outstanding	3.5	6.7	7.2	8.1	13.0	8.8	32.3	40.0

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

© Copyright 2020, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE

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



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

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, John Vandermosten, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

© Copyright 2020, Zacks Investment Research. All Rights Reserved.