Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

August 7, 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)

Fourth Quarter Start for ORCA-2

Based on our DCF model and a 15% discount rate, ACHV is valued at approximately $40.00 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 (8/6/2020)	$11.70
Valuation	**$40.00**

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 expected to start in 4Q: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	**50.20**
52-Week Low	**4.60**
One-Year Return (%)	**-66.6**
Beta	**1.81**
Average Daily Volume (sh)	**1,468,371**
Shares Outstanding (mil)	**3.59**
Market Capitalization ($mil)	**42.0**
Short Interest Ratio (days)	**1.3**
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 A	$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	-$17.57 A	-$10.08 A	-$9.07 A	-$5.91 A	-$39.76 A
2020	-$2.15 A	-$1.68 A	-$1.30 E	-$2.54 E	-$7.82 E
2021					-$7.25 E
2022					-$5.96 E

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

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

WHAT'S NEW

Second Quarter 2020 Review

Achieve Life Sciences, Inc. (NASDAQ: ACHV) reported second quarter results in a press release and conference call held on August 6, 2020. The company concurrently filed its 10-Q with the SEC. During the second quarter and to date, Achieve has raised additional capital, provided favorable topline data from the RAUORA trial, filed additional patents for novel analogs of cytisinicline and provided an update for the start of the Phase III ORCA-2 trial. Achieve has submitted all required documents to the FDA and anticipates starting the Phase III ORCA-2 trial in 4Q:20.

Second Quarter 2020 Financial Performance

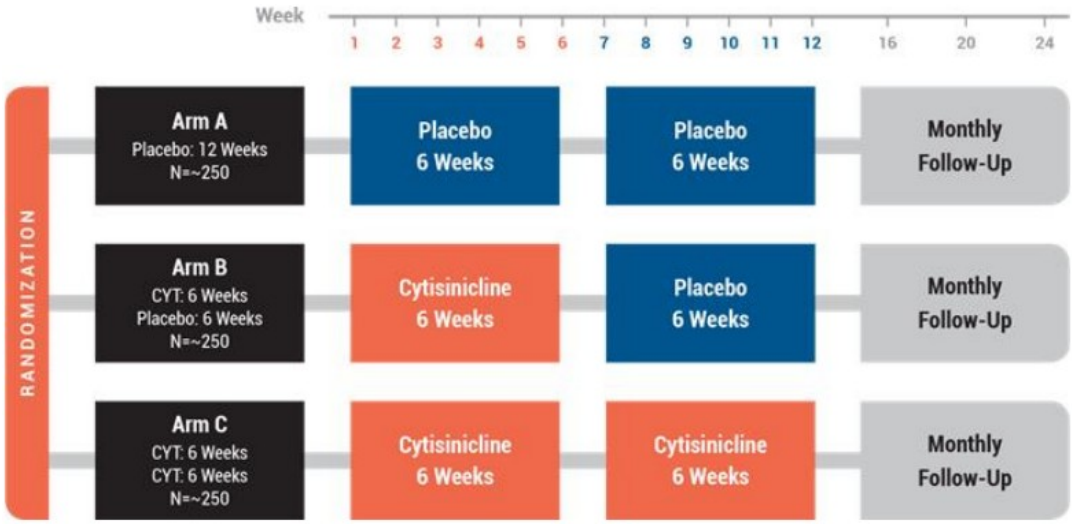
Research and development expenses totaled $1.1 million in 2Q:20, down 46% compared with 2Q:19 due to the completion of the ORCA-1 trial last year. General and administrative expenses for the quarter were $1.8 million, up 11% over second quarter 2019 levels. This line item increased due to additional market research and public relations activities and was partially offset by lower travel costs as a result of pandemic-related travel restrictions across the U.S and other countries. Net loss for 2Q:20 was ($2.9) million or ($1.68) per share on a weighted average share count of 1.74 million. Share balance reflects the 1:20 split effective July 31, 2020.

Cash burn was ($2.2) million for the second quarter, compared with ($3.9) million in the comparable prior period. Cash and equivalents and short-term investments as of June 30, 2020 were $12.1 million, essentially even with first quarter levels. $2.2 million in net financing proceeds were received from the April private placement and warrant exercise proceeds. Following the end of the quarter, $2.3 million in additional cash proceeds were generated from the exercise of options. A registered direct offering raised an additional $6 million in late June and a public offering grossed $6.5 million in early August bringing pro forma cash on hand to $26.7 million.

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. The trial will be a multi-center, double-blind, randomized, placebo-controlled Phase III study that will enroll 750 adult cigarette smokers who intend to quit smoking. Subjects will be randomized into one of three arms which appear in the subsequent exhibit. We anticipate a 4Q:20 start for the first of the two Phase III cytisinicline studies. Dosing is anticipated to be 3.0 mg, three times daily in both the six- 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 last December to finalize trial details to ensure protocol modifications meet the agency's approval. We anticipate a 4Q:20 start for ORCA-2.

Exhibit I – Phase III Trial Design[1]



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

The primary endpoints for the ORCA-2 study will be the rate of smoking abstinence at the end of 6- and 12-week treatment periods compared to placebo. Abstinence will be defined as no smoking during the last four weeks of treatment using weekly CO biochemical verification. Secondary endpoints will be based upon continued smoking abstinence until week 24 from the end of treatment and identify a reduction in the risk of relapse for subjects on the 6 week treatment regimen compared to the 12 week. Efforts have been made to prepare sites to comply with COVID-19 restrictions. All required non-clinical submissions necessary to start the trial have been completed.

RAOURA Study

In June, topline results for the New Zealand RAUORA[2] study were made available without quantification. The trial achieved statistical significance in demonstrating that cytisinicline and behavioral support were at least as effective as varenicline[3] plus behavioral support at six months. Cytisinicline showed significantly fewer reported adverse events compared with varenicline in the study. RAUORA enrolled 2,140 Māori and their extended family in a randomized, non-inferiority trial. It is expected that full results will be presented at the fall SRNT conference in September 2020. This head to head trial comparing cytisinicline and varenicline is expected to demonstrate superior safety and efficacy for Achieve's in-development product and will provide commercialization justification. Under the new simplified and higher dosing regimen for 12 weeks, results could even further differentiate cytisinicline from varenicline in the ORCA-2 trial as subjects will be on drug for both products when endpoints are measured. We published an article discussing details on the study available here.[4]

Capital Raise

In April 2020, Achieve issued shares of stock in a private placement that raised gross proceeds of $1.9 million. Paulson Investment Company acted as the placement agent. The deal included 75% warrant coverage, with warrants carrying a five year life. Additional broker warrants were also issued. 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.

Following the end of the second quarter, Achieve completed a registered direct offering of 731,707 shares at $8.20 per share on July 1, 2020. This effort raised gross proceeds of $6.0 million and net funds of $5.5 million. On August 3rd, 2020, Achieve announced a public offering of 712,000 shares and pre-funded warrants for $10.50 per unit. The effort is expected to raise $7.5 million gross and $6.8 million in net proceeds. The underwriter has an option to purchase 93,000 additional shares.

Valuation

At the end of July 2020, Achieve effected a 1:20 reverse stock split and additional shares were issued as a result of new capital raises and warrant exercise. We update our valuation to reflect these changes and note there is no material change to our enterprise value compared with our prior report. Our updated price target is $40 per share.

Key Events

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

[2] Rauora is the Māori word for rescue
[3] Branded Chantix from Pfizer in the United States
[4] https://scr.zacks.com/News/Press-Releases/Press-Release-Details/2020/ACHV-RAUORA-Cytisiniclines-Superior-Side-Effect-Profile/default.aspx

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 fourth quarter 2020 start to the ORCA-2 trial. Achieve has an attractive product that has demonstrated non-inferior efficacy and improved safety compared to the market leader. We think prospective partners with a primary care salesforce and other infrastructure already in place will be interested in acquisition. 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 start of the first of two Phase III trials in 4Q:20. Based on our conservative estimates, shares of ACHV are undervalued relative to their potential. Our valuation of Achieve is $40.00 per share.

PROJECTED FINANCIALS

Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2019 A	Q1 A	Q2 A	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	$1.1	$2.0	$7.5	$12.1	$21.0	$21.5
G&A	$6.9	$1.8	$1.8	$1.9	$1.9	$7.4	$8.0	$8.3
Operating Income	($16.5)	($3.4)	($2.9)	($3.9)	($9.4)	($19.6)	($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)	($2.9)	($3.9)	($9.4)	($19.5)	($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)	($2.9)	($3.9)	($9.4)	($19.5)	($29.0)	($29.8)
Reported EPS	**($39.76)**	**($2.15)**	**($1.68)**	**($1.30)**	**($2.54)**	**($7.82)**	**($7.25)**	**($5.96)**
YOY Growth								
Shares Outstanding	0.412	1.547	1.744	3.000	3.700	2.498	4.000	5.000

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[5]



[5] Source: Zacks Research System

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 views 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.