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Achieve Life Sciences, Inc. (ACHV - NASDAQ)

SRNT Presentation Next on Agenda

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 (8/8/2019)	$1.85
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 will provide detailed data in September.

Two Ph3 studies are planned in up to 2,300 patients with the first starting in late 2019 and the second in first half 2020. The trials will compare cytisinicline with placebo combined with counseling. The primary endpoint is abstinence at two months with follow-up to six months.

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

SUMMARY DATA

52-Week High	**5.25**
52-Week Low	**1.04**
One-Year Return (%)	**-45.9**
Beta	**1.76**
Average Daily Volume (sh)	**203,431**
Shares Outstanding (mil)	**8.1**
Market Capitalization ($mil)	**15.0**
Short Interest Ratio (days)	**2.34**
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 E	$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	-$0.22 E	-$0.20 E	-$1.36 E
2020					-$1.16 E
2021					-$0.81 E

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WHAT'S NEW

Second Quarter 2019 Operational and Financial Results

Achieve Life Sciences, Inc. (NASDAQ: ACHV) released its second quarter results for 2019 and filed the companion 10-Q on August 8, 2019. An investor conference call was held following the release to discuss recent achievements and financial results. No revenues were reported for the development stage company and operational expenses totaled $3.7 million producing a net loss of ($0.50) per share. During the three month period, the company completed the ORCA-1 Phase IIb study, was granted a patent for a new formulation of cytisinicline and reported statistically significant improvement in quit rates for cytisinicline. After the end of the reporting period, Achieve publicized the continued collaboration with the NIH which is conducting several NDA-enabling studies for cytisinicline.

Research and development expense of $2.0 million rose 94% from the $1.0 million spent in 2Q:18. The increase was attributable to spending on the ORCA-1 trial, which was launched in October 2018 and was completed in June 2019. General and administrative expenses were $1.6 million in the three month period, declining from $1.8 million during the prior year period. The 7% fall was attributable to lower rent and facilities operating expenses. Net loss for 2Q:19 was ($3.6) million or ($0.50) per share on a weighted average share count of 7.19 million.

Cash burn was ($3.9) million in 2Q:19, compared to ($1.9) million in 1Q:18 due to higher levels of trial activity related to completing ORCA-1 and other trial work. Cash and equivalents and short-term investments as of March 31, 2019 were $10.5 million, a sequential increase due to $4.2 million in warrant proceeds more than offsetting operating expenses. As of August 8, 2019, 8.10 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 had 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

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

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 highest daily dose to date used in the trials has been 21 mg with no evidence of dose limiting toxicity. The Data Safety Monitoring Committee (DSMC) recommended that the protocol be amended to examine higher doses, up to 30 mg, which required and received ethics committee approval. The lack of evidence of serious side effects provides additional evidence of safety for cytisinicline.

Cytisinicline Patent Granted

In May, Achieve announced the grant of a patent by the US Patent and Trademark Office for a novel salt of cytisine that increases the stability of the molecule and can potentially improve its shelf life. The patent has already been granted in the United Kingdom and is pending in other major jurisdictions. The patent may enable Achieve to avoid competition in successive iterations of cytisinicline. As a reminder, naturally occurring substances such as cytisine are not patentable and may only receive exclusivity from regulatory agencies following approval. The patent will likely not be applicable to the current smoking cessation indication of cytisinicline as previous clinical trials would have to be repeated; however, it does set up the portfolio for other indications that may be pursued at a later date.

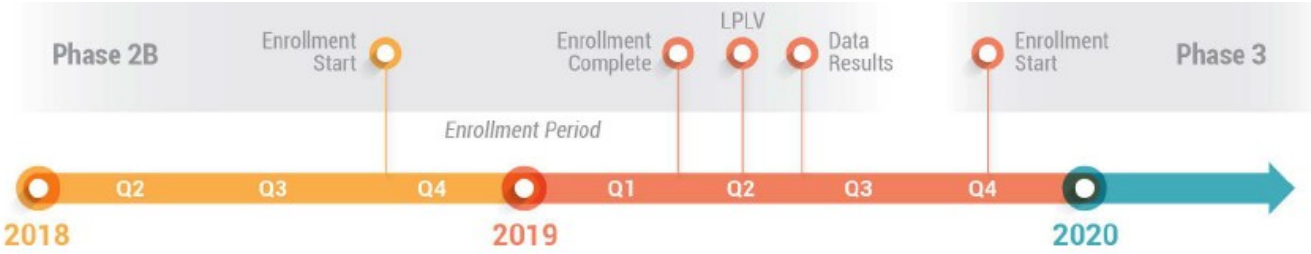
Phase III Trial

Achieve is on track to start its Phase III trial in the second half of 2019. There are trial design issues that are being finalized with the FDA and will be guided by the results of the ORCA-1 and other trials being conducted. The areas to be confirmed include trial execution, statistical powering and optimal dosing. It is this last component which is most interesting given the dose response observed in the PK/PD study. To explore dose efficacy more thoroughly, a MTD study was launched in March. Competitor varenicline was dose limited by the off-target effects (most commonly nausea) that we discussed in our initiation, a profile that cytisinicline may not have.

Key Events

- Last patient enrolled in Phase IIb – February 2019
- Repeat dose final study final results release – 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 Society for Research on Nicotine & Tobacco (SRNT) meeting – September 2019
- Final Study Results for MTD Study – 3Q:19
- FDA End of Phase II Meeting – 4Q:19
- Launch 800 person Phase III trial – 4Q:19
- Launch 1,500 person Phase III trial – first half 2020
- Complete 800 person Phase II trial 4Q:20
- Complete 1,500 person Phase III trial – year end 2021
- Submit NDA to FDA – 2022
- FDA response and launch of cytisinicline - 2023

Exhibit II – Planned Development Program and Milestones



Activity	Anticipated Timing
First patient enrolled P2b	Q4 2018
Last patient enrolled P2b	Q1 2019
Repeat Dose Study Final Study Results	Q1 2019
Maximum Tolerated Dose (MTD) Study Initiation	Q1 2019
Top line results P2b	Q2 2019
MTD Study Results	Q3 2019
Phase 3 Trial Initiating	Q4 2019

ORCA Ongoing Research of Cytisinicline for Addiction

Summary

We believe that the long historical use of cytisinicline which has been confirmed in the dose ranging study provides confidence that the upcoming Phase III trials will be successful and 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 holds sufficient capital on its balance sheet to complete the Phase IIb trial and other ongoing studies. However, additional capital will be needed to launch the two Phase III studies which are anticipated to begin before year end. We anticipate a capital raise after successful data from the ORCA-1 trial is released. There is also the potential to work with a partner who has a primary care salesforce and other infrastructure already in place. 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 big milestone on the horizon is presentation of data at the SRNT conference in Oslo, Norway in September. 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 E	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	$1.6	$2.8	$10.5	$26.0	$21.0
G&A	$6.9	$1.9	$1.6	$1.8	$1.8	$7.1	$7.6	$8.0
Operating Income	($12.8)	($5.9)	($3.7)	($3.4)	($4.6)	($17.6)	($33.6)	($29.0)
Interest Income	$0.2	$0.0	$0.0	$0.1	$0.1	$0.2	$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)	($3.3)	($4.5)	($17.3)	($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)	($3.3)	($4.5)	($17.3)	($33.6)	($29.0)
Reported EPS	**($3.61)**	**($0.88)**	**($0.50)**	**($0.22)**	**($0.20)**	**($1.36)**	**($1.16)**	**($0.81)**
YOY Growth								
Shares Outstanding	3.5	6.7	7.2	15.0	22.0	12.7	29.0	36.0

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

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HISTORICAL STOCK PRICE

Achieve Life Sciences, Inc. – Stock Price Chart[1]

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

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