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Achieve Life Sciences, Inc. (ACHV: NASDAQ)

ACHV: Ancillary Studies Complete

We employ a DCF model and a 15% discount rate to generate our valuation. Our model applies a 70% probability of eventual cytisinicline sales based on historical Phase III trial success ratios, trial progress and data generated to date. Our valuation includes geographic contributions only from the United States.

Current Price (11/9/2023)	$4.19
Valuation	**$56.00**

OUTLOOK

Achieve Life Sciences is developing cytisinicline for use as a smoking cessation treatment in the United States and rest of world. Topline results from ORCA-2 were reported in April 2022 and for ORCA-3 in May 2023. Results exceeded expectations on safety & efficacy parameters.

Both Phase III trials compare cytisinicline with placebo combined with counseling. The primary endpoint is abstinence at 6 & 12 weeks for the last 4 weeks of treatment. A Phase II trial in vaping cessation (ORCA-V1) reported topline in April 2023.

Existing cessation products provide limited effectiveness and produce unpleasant side effects including nausea, vivid dreams, insomnia & GI issues. Cytisinicline may fill a void in the prescription & NRT market by reducing nicotine cravings, severity of withdrawal & reward associated with smoking along with fewer side effects & 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. We anticipate a 2025 commercialization of cytisinicline.

SUMMARY DATA

52-Week High	**10.30**
52-Week Low	**2.01**
One-Year Return (%)	**105**
Beta	**1.4**
Average Daily Volume (sh)	**41,349**
Shares Outstanding (mil)	**21.2**
Market Capitalization ($mil)	**88.8**
Short Interest Ratio (days)	**19.3**
Institutional Ownership (%)	**30.7**
Insider Ownership (%)	**7.8**
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 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2024					$0.0 E
2025					$97.1 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.80 A	-$1.09 A	-$1.35 A	-$0.83 A	-$4.00 A
2023	-$0.50 A	-$0.43 A	-$0.34 A	-$0.28 E	-$1.53 E
2024					-$1.55 E
2025					$2.24 E

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WHAT'S NEW

Third Quarter 2023 Results

Achieve Life Sciences, Inc. (NASDAQ: ACHV) reported third quarter 2023 results in a press release on November 9th after market close and subsequently held a conference call discussing recent accomplishments. The company concurrently filed its Form 10-Q with the SEC. Highlights since the second quarter earnings call include attendance at investor conferences and presentation of results at scientific conferences including vaping results at SRNT Europe. The company also completed dosing in three ancillary clinical studies and held a pre-new drug application (NDA) meeting with the FDA. We expect to see a refinement in expectations for the NDA application following written responses from the drug agency which are expected in the next few weeks.

2023 achievements:

- Presentation at SRNT Annual Meeting – March
- Board of Director additions – March
- ORCA-V1 clinical trial results – April
- Refinancing of SVB Loan – May
- ORCA-3 topline results – May
- $16.5 million registered direct offering – May
- ORCA-2 smoking cessation trial published in JAMA – July
- Presentation at the American Society of Pharmacognosy 2023 Annual Meeting – July
- Presentation of ORCA-V1 results at SRTN Europe – September

No revenues were reported for 3Q:23. Operating expense was $6.6 million yielding a net loss of ($7.1) million or ($0.34) per share. For the quarter ending September 30, 2023 and versus the same comparable period in the prior year:

- Research & development expense totaled $3.6 million, down 64% from $9.9 million, as expenses in the prior year related to ORCA-3 and ORCA-V1 fell substantially and spending shifted towards the three ancillary support studies required for cytisinicline NDA submission and FDA preparatory efforts;
- General & administrative expense was $3.0 million, up 8% from $2.8 million on higher employee expenses associated with stock-based compensation and higher legal expenses as a result of general corporate activities. The increased expenses were partially offset by a decrease in costs associated with clinical trial media and awareness as both the ORCA-3 trial and ORCA-V1 trial were fully enrolled in the third and fourth quarter of 2022, respectively, and lower patent filing expenses as a result of a decrease in patent associated activities in 2023;
- Net interest expense was ($519,000) vs. ($408,000) due to a higher debt balance and higher floating interest rates;
- Net loss was ($7.1) million vs. ($13.1) million or ($0.34) and ($1.35) per share, respectively.

As of September 30, 2023, cash and equivalents totaled $19.9 million. This amount compares to a $24.8 million balance in cash and equivalents held at the end of 2022. Achieve has assumed $15 million of convertible debt related to its loan facility originally with SVB and now with First Citizens Bank & Trust Company. It is carried at $16.2 million on the balance sheet and includes accrued interest. The term loan was modified in May and now matures in December 2024. 3Q:23 cash used in operations was ($5.2) million versus ($11.3) million in the prior year period. Achieve anticipates having sufficient cash to support operations until 2H:24.

New Drug Application (NDA) Preparation

Now that ORCA-3 has concluded, focus has shifted towards the three ancillary trials that must be completed for inclusion with the upcoming new drug application (NDA). These studies are investigating QT interval prolongation, steady-state pharmacokinetics in smokers and pharmacokinetics parameters in subjects with renal impairment. Clinical work has been completed and data compilation and analysis are underway. Management anticipates that final study reports will be completed in early 2024.

Achieve has also been in close contact with the FDA and held a pre-NDA meeting with the agency in October to review what data will be acceptable for submission. According to management, agreement was reached on many of the submission requirements and Achieve is waiting for resolution of matters still under discussion. The company will provide updated timing on next steps and ultimate submission after receiving written responses from the agency.

In parallel with the clinical work with the FDA, Achieve is also in close collaboration with Sopharma regarding the preparation of its drug manufacturing facilities for inspection. As we have previously discussed, Achieve and Sopharma have conducted mock inspections and engaged consultants in preparation for the regulatory review.

Partnership Discussions

Since the May 2023 topline readout of the final pivotal trial for cytisinicline approval in smoking cessation, management and investor attention has turned to partnership opportunities. We have maintained in our expectations that a partnership with a large global pharma supplying a primary sales force already in place makes the most sense for the exit strategy. While Achieve management has not given many clues regarding their partnership discussions, CEO John Bencich noted that the team has conducted further outreach and discussions with commercial organizations that have a global reach and discussions continue with multiple parties.

Varenicline

Endo Pharmaceuticals' subsidiary, Par Pharmaceuticals began selling a generic version of Pfizer's Chantix (varenicline) in September 2021. It was granted temporary exclusivity but is now facing competition from others. Endo noted in its latest filing that several competitors had entered the market. Recently, Zydus Pharmaceuticals launched its generic version of varenicline and was sued by Endo as reported in a recent article. We see interest in smoking cessation medication as a strong positive for cytisinicline and believe that the superior safety profile for Achieve's product will strongly support market entry.

Vaping Results Presented at SRNT

Dr. Nancy Rigotti, ORCA-V1's principal investigator, presented results from the cytisinicline e-cigarette cessation trial at the Society for Research on Nicotine and Tobacco Europe (SRNT-E) Annual Meeting in London in mid-September. Results from the ORCA-V1 were presented at the conference along with additional findings. See our May 10th, 2023 report for a summary of vaping trial results.

Additional analyses shared at the conference showed that vaping abstinence with cytisinicline treatment started by the second week of treatment, with the odds of vaping cessation improving throughout the 12-week treatment period. The odds of vaping cessation for cytisinicline were 1.8 times, 2.2 times, and 2.6 times higher than placebo at Week 3-6, Week 6-9, and Week 9-12, respectively. During the Week 12-16 follow-up period, subjects treated with cytisinicline continued to demonstrate 2.0 times higher odds of vaping cessation compared to placebo.

Publications

Achieve's ORCA-2 results were published in the July issue of the Journal of the American Medical Association (JAMA). Cytisinicline for Smoking Cessation highlighted the results of the 810 subject trial concluding that Both 6- and 12-week cytisinicline schedules, with behavioral support, demonstrated smoking cessation efficacy and excellent tolerability, offering new nicotine dependence treatment options.

Summary

Achieve continues to march forward and systematically address all of the tasks required for a successful exit. Regulatory meetings have been fruitful and preparations for NDA submission, including the completion of several required ancillary trials, are done or underway. Preparations at Sopharma's manufacturing plant for FDA inspection are ongoing and there are active discussions with potential suitors. Achieve management highlighted its near-term objectives which include finalizing discussions with preferred strategic commercial organizations, completing preparations for an NDA submission and identifying a pathway for cytisinicline label expansion into non-combustible nicotine cessation. The company's prospects continue to be bright and we maintain our target price of $56.

PROJECTED FINANCIALS

Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2022 A	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$97.1**
R&D	$30.1	$5.5	$4.6	$3.6	$3.0	$16.7	$8.0	$6.0
G&A	$10.7	$3.0	$3.1	$3.0	$3.0	$12.2	$22.0	$28.0
Operating Income	($40.8)	($8.6)	($7.7)	($6.6)	($6.0)	($28.9)	($36.0)	$54.9
Operating Margin								*56.6%*
Interest Income	$0.2	($0.4)	($0.5)	($0.5)	$0.0	($1.4)	$0.0	$0.0
Total Other Income	($1.7)	($0.0)	($0.0)	($0.0)	$0.0	($0.0)	$0.0	$0.0
Pre-Tax Income	($42.4)	($9.0)	($8.2)	($7.1)	($6.0)	($30.3)	($36.0)	$54.9
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%*
Net Income	($42.4)	($9.0)	($8.2)	($7.1)	($6.0)	($30.3)	($36.0)	$54.9
Reported EPS	**($4.00)**	**($0.50)**	**($0.43)**	**($0.34)**	**($0.28)**	**($1.53)**	**($1.55)**	**$2.24**
Shares Outstanding	10.593	17.9	19.0	21.1	21.4	19.9	23.2	24.5

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

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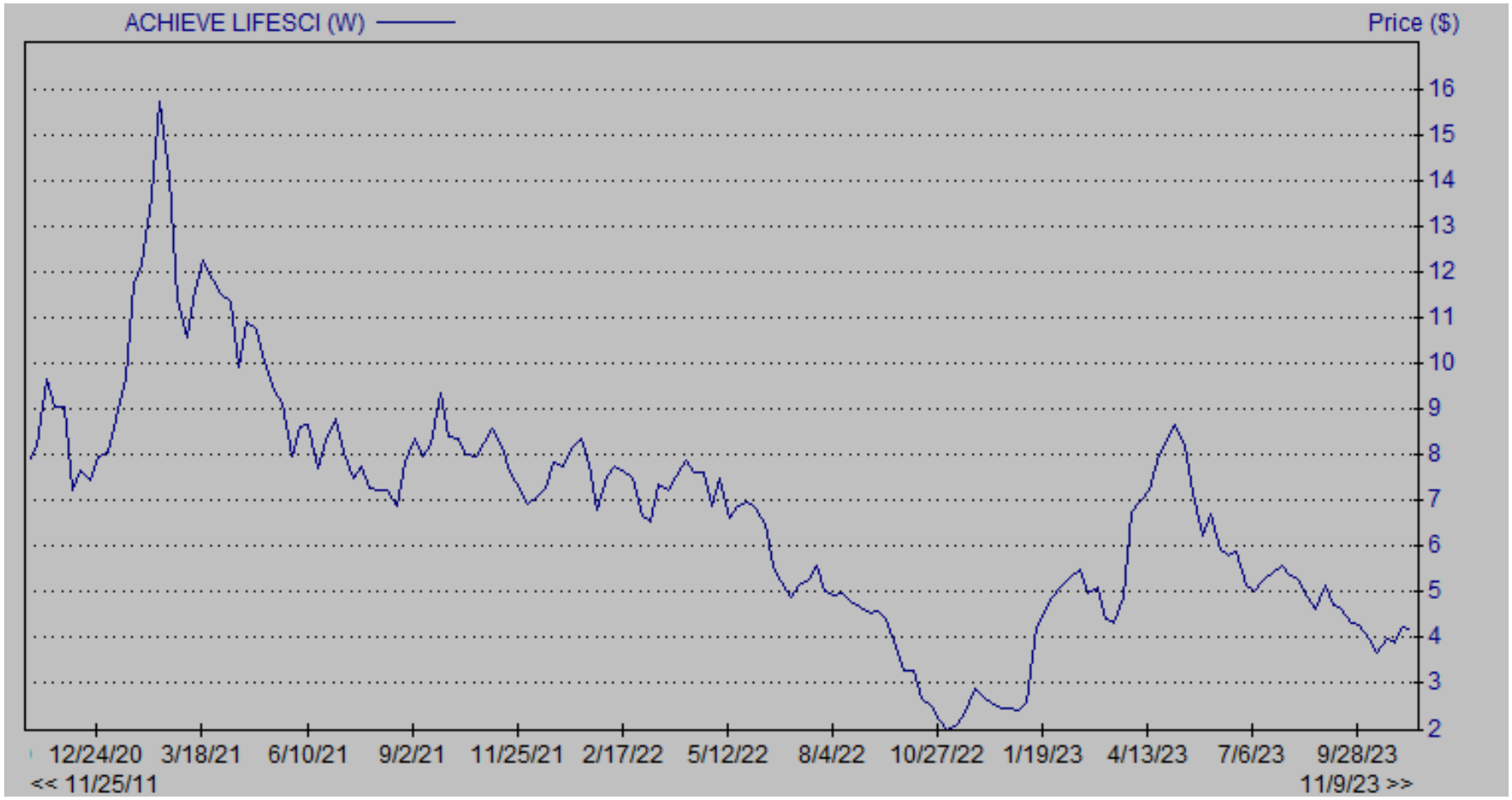
HISTORICAL STOCK PRICE

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



[1] Source: Zacks Research System

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