Zacks Small-Cap Research

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Achieve Life Sciences, Inc. (ACHV: NASDAQ)

ACHV: Kicking Butts to Achieve June NDA Filing

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 rates, trial progress and data generated to date. Our valuation includes geographic contributions only from the United States.

Current Price (5/13/2025)	$2.65
Valuation	**$30.00**

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. Achieve is conducting the ORCA-OL safety trial which should support an NDA submission by 1H:25 and has completed the six-month portion.

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 III 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 2026 commercialization of cytisinicline.

SUMMARY DATA

52-Week High	**5.59**
52-Week Low	**1.84**
One-Year Return (%)	**-44.9**
Beta	**1.5**
Average Daily Volume (sh)	**181,475**
Shares Outstanding (mil)	**34.8**
Market Capitalization ($mil)	**92.2**
Short Interest Ratio (days)	**11.6**
Institutional Ownership (%)	**43.0**
Insider Ownership (%)	**9.9**
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 2025 Estimate	**N/A**
P/E using 2026 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)
2024	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2025	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2026					$20.1 E
2027					$104 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	-$0.26 A	-$0.25 A	-$0.36 A	-$0.36 A	-$1.24 A
2025	-$0.37 A	-$0.37 E	-$0.22 E	-$0.23 E	-$1.11 E
2026					-$1.07 E
2027					$0.69 E

WHAT'S NEW

Achieve Life Sciences, Inc. (NASDAQ: ACHV) reported its first quarter 2025 results, highlighting progress on the ORCA-OL study, preparation of the New Drug Application (NDA) for cytisinicline, and efforts on further commercialization planning. The company has refined its anticipated NDA submission to June 2025 which, assuming historical timelines, would generate an FDA action date in the second quarter of 2026. Notably, results from the ORCA-3 study were published in JAMA Internal Medicine, presenting detailed safety and efficacy data for cytisinicline since the previous financial update.

Financial and Operational Results

Achieve's first quarter 2025 financial and operational results were provided in a press release, filing of Form 10-Q and a webcast which provided an opportunity for analysts to ask questions. No revenues were reported in 1Q:25. Operating expense was $12.9 million producing a net loss of ($12.9) million or ($0.37) per share. For the quarter ending March 31st, 2025 and versus the same comparable prior year quarter:

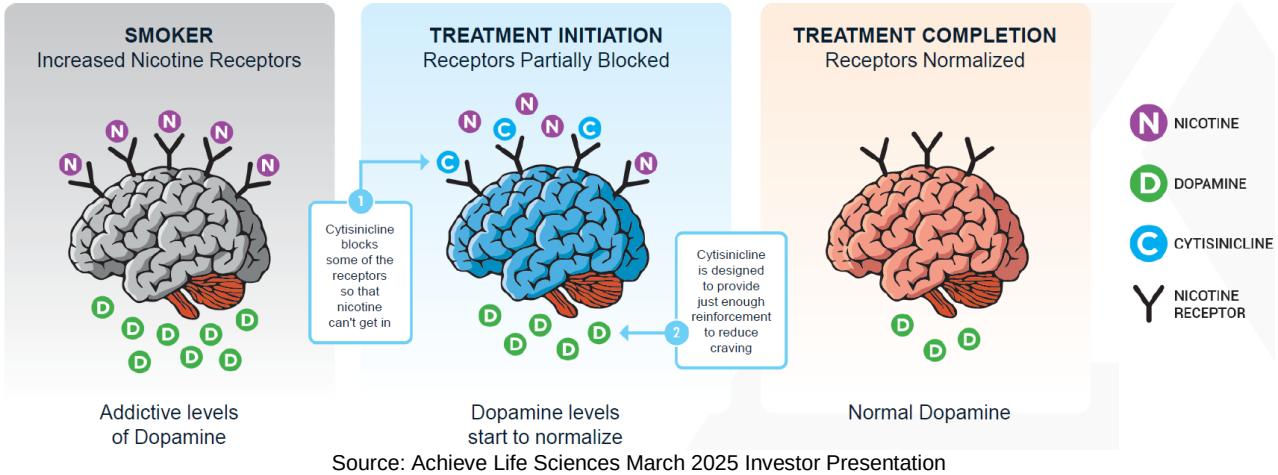
- Research & development expense totaled $7.1 million, up 154% from $2.8 million, due to the initiation and enrollment of the ORCA-OL safety trial in May 2024;
- General & administrative expense was $5.8 million, up 82% from $3.2 million on higher employee expenses and commercial launch preparation;
- Net other expense was $67,000 vs. ($512,000) as interest income offset interest expense and net other miscellaneous items;
- Net loss was ($12.9) million vs. ($6.5) million or ($0.37) and ($0.26) per share, respectively.

As of March 31st, 2025, cash and equivalents totaled $23.2 million. This compares to a $34.4 million balance held at the end of 2024. Achieve carries convertible debt of $9.9 million on the balance sheet which includes accrued interest. The company refinanced its debt agreement with Silicon Valley Bank (SVB), extending maturity until the end of 2027. Achieve is eligible to draw an additional $5 million from the facility following FDA acceptance of its NDA. Cash used in operations during 1Q:25 was ($11.1) million versus ($5.3) million in the same prior year period. Management estimates that the company has sufficient cash to support operations until 3Q:25.

JAMA Internal Medicine Publication

In April, JAMA Internal Medicine published an article titled Cytisinicline for Smoking Cessation: The ORCA Phase 3 Replication Randomized Clinical Trial. The article described cytisinicline as a safe and effective smoking cessation treatment that reduces nicotine cravings. The article summarized the ORCA-3 trial design and reviewed its results. The trial measured smoking abstinence for 792 participants that were either given cytisinicline or placebo for either six or twelve weeks. Results were verified by biochemical measurement. For six-week treatment, 14.8% of the cytisinicline participants vs. 6.0% of the placebo participants were abstinent during weeks 9 to 12. This generated an odds ratio of 2.9. For 12-week treatment, 30.3% of the cytisinicline participants vs. 9.4% of the placebo participants were abstinent during weeks 9 to 12. This generated an odds ratio of 4.4.

Exhibit I – Cytisinicline's Dual-Acting Mechanism of Action



Source: Achieve Life Sciences March 2025 Investor Presentation

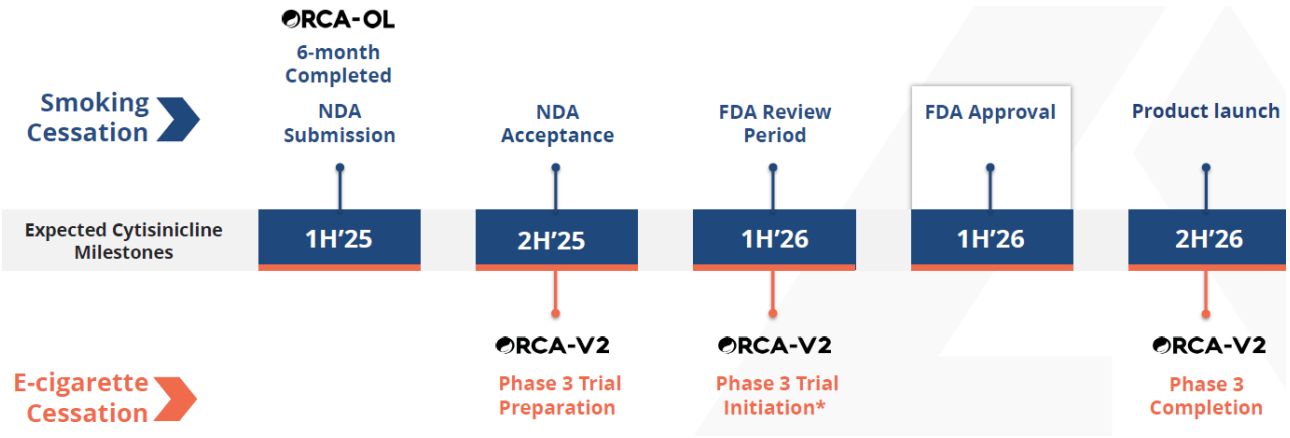
ORCA-OL Safety Trial

Achieve began the year with good news for ORCA-OL, announcing that 300 participants had completed six months of treatment in the Ongoing Research of Cytisinicline for Addiction Program, Open Label (ORCA-OL) trial. The Data Safety Monitoring Committee (DSMC) identified no safety concerns as of this milestone allowing registrational filing with the FDA. As of May 2025, a third DSMC safety review was completed which also found no unexpected treatment-related adverse events. As of the first quarter reporting date, more than 100 subjects had completed one year of cytisinicline treatment. Furthermore, about 75% of the 479 (~360) individuals remain on treatment in the trial. We think that it is a material real-world positive that so many participants would remain on a smoking cessation product for that long a period suggesting that cytisinicline is well tolerated. This is particularly notable given the high discontinuation rates for Chantix and the associated unpleasant side effects such as nausea, headache, abnormal dreams and constipation.[1] Achieve plans to submit its NDA to the FDA in June 2025.

Milestones

- Launch of ORCA-OL trial – May 2024
- ORCA OL enrollment completed – October 2024
- Development of cytisinicline product label for smoking cessation – 1H:25
- Completion of six months of ORCA-OL safety data for 300 subjects – January 2025
- Attendance at Oppenheimer Healthcare Life Sciences Conference, Virtual – February 2024
- Attendance at Barclays Healthcare Conference, Miami – March 2025
- Selection of 3rd party logistics partner – 2Q:25
- NDA Submission – 2Q:25
- Data from 100 patients with twelve months exposure to cytisinicline – mid-2025
- Launch of Phase III vaping trial – 1H:26
- FDA target action date for cytisinicline NDA – 1H:26
- Launch of cytisinicline – 3Q:26

Exhibit II – Achieve Development Timeline



Source: Achieve March 2025 Corporate Presentation

Summary

Achieve provided a financial and operational update highlighting the advances made over the last two months continuing the ORCA-OL trial, preparing the NDA for submission in June and looking ahead to next steps for the vaping indication. While the team is moving forward under the assumption that it will commercialize cytisinicline itself, an established pharmaceutical company could either buy out the company or license all or part of the available geographies. We see cytisinicline as a material improvement over existing nicotine cessation products with substantially reduced side effects, which allows patients to complete their course of therapy and reap the benefits of the naturally derived product. We maintain our valuation of $30 per share.

[1] Minian, N., *et al*. Identifying determinants of varenicline adherence using the Theoretical Domains framework: a rapid review. BMC Public Health. March 2024.

PROJECTED FINANCIALS

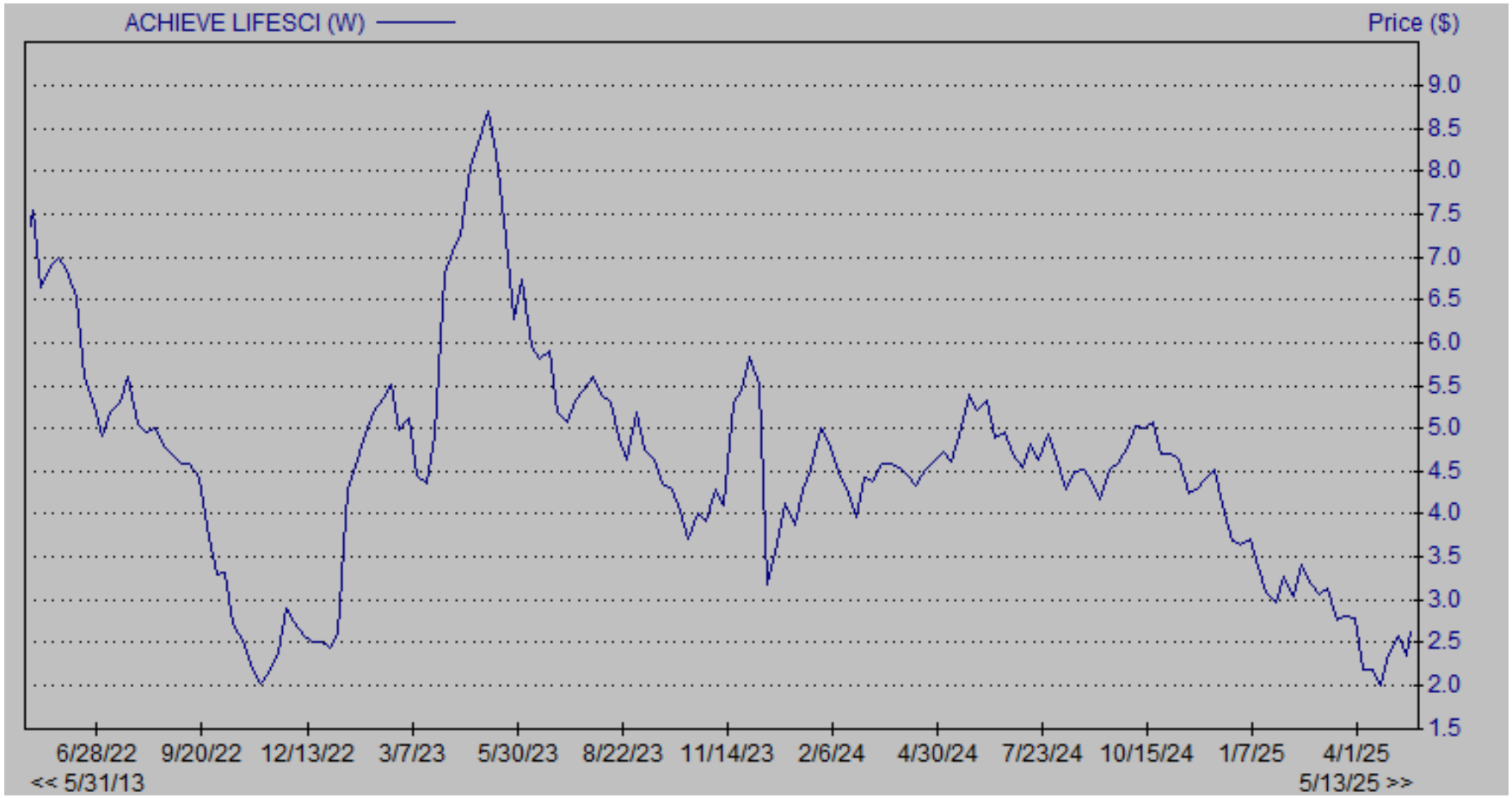
Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2024 A	Q1 A	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$20.1**	**$103.6**
Growth	-					-	-	417%
R&D	$22.8	$7.1	$5.4	$3.5	$1.8	$17.8	$29.0	$0.0
G&A	$16.3	$5.8	$6.2	$7.4	$8.6	$28.0	$29.0	$29.6
S&M	$0.0	$0.0	$1.1	$2.0	$3.0	$6.1	$26.1	$31.5
Operating Income	($39.1)	($12.9)	($12.7)	($12.9)	($13.4)	($51.9)	($64.1)	$42.6
Operating Margin							*-319.4%*	*41.1%*
Interest Income	$0.2	$0.3	$0.2	$0.1	$0.7	$0.0	$0.0	$0.0
Total Other Income	($0.9)	($0.3)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($39.8)	($12.8)	($12.5)	($12.8)	($12.7)	($51.9)	($64.1)	$42.6
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	($39.8)	($12.9)	($12.5)	($12.8)	($12.7)	($51.9)	($64.1)	$42.6
Reported EPS	**($1.24)**	**($0.37)**	**($0.36)**	**($0.22)**	**($0.22)**	**($1.11)**	**($1.07)**	**$0.69**
YOY Growth								
Shares Outstanding	32.1	34.7	34.7	58.0	59.0	46.6	59.7	62.0

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

HISTORICAL STOCK PRICE

Achieve Life Sciences, Inc. – Stock Price Chart[2]



[2] Source: Zacks Research System

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