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Achieve Life Sciences, Inc. (ACHV: NASDAQ)

ACHV: 2Q:25 NDA Submission

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 (3/11/2025)	$2.92
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	**2.82**
One-Year Return (%)	**-32.9**
Beta	**1.7**
Average Daily Volume (sh)	**239,863**
Shares Outstanding (mil)	**34.8**
Market Capitalization ($mil)	**101.6**
Short Interest Ratio (days)	**11.7**
Institutional Ownership (%)	**57.7**
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 2024 Estimate	**N/A**
P/E using 2025 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)
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2024	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2025					$0.0 E
2026					$50.2 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.50 A	-$0.43 A	-$0.34 A	-$0.21 A	-$1.50 A
2024	-$0.26 A	-$0.25 A	-$0.36 A	-$0.36 A	-$1.24 A
2025					-$0.93 E
2026					$0.08 E

WHAT'S NEW

Achieve Life Sciences, Inc. (NASDAQ: ACHV) reported 2024 results sharing progress with the new drug application (NDA) for cytisinicline and narrowing its anticipated submission date to late 2Q:25. Chief Medical Officer Dr. Jacobs and her team are compiling the various required components for the document and are ensuring that all the required steps are completed. Over the last few months, Achieve has added new board members and executives and completed the initial portion of its ORCA-OL study which will generate critical safety data to be included in the NDA for smoking cessation. The R&D team held the end of Phase II (EoP2) meeting with the FDA to finalize the study design for the pivotal vaping trial. Management has shared its recent accomplishments at investor events including the Jefferies London Healthcare conference in November and the Piper Sandler Healthcare conference in December in New York. Management also participated in one-on-one meetings during the JP Morgan Healthcare Conference in San Francisco in January and the Barclays Healthcare Conference the day after the earnings report.

Financial and Operational Results

Achieve's 2024 financial and operational results were provided in a press release, filing of Form 10-K and a webcast which provided an opportunity for analysts to ask questions. No revenues were reported for 2024. Operating expense was $39.1 million producing a net loss of ($39.8) million or ($1.24) per share. For the year ending December 31st, 2024 and versus the same comparable prior year period:

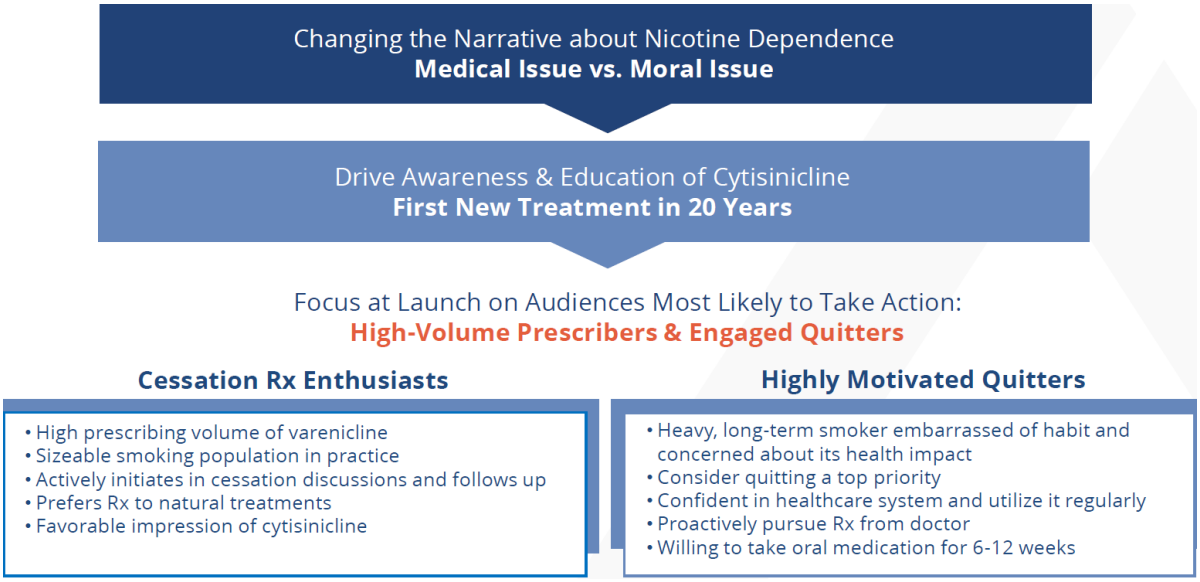
- Research & development expense totaled $22.8 million, up 44% from $15.8 million, due to the initiation and enrollment of the ORCA-OL open label safety trial in May 2024;
- General & administrative expense was $16.3 million, up 42% from $11.4 million on higher employee expenses, including commercial launch preparation costs, severance costs, consulting costs and legal expenses associated with patent activities and general corporate activities;
- Net other expense was ($758,000) vs. ($2.6) million as interest income was more than offset by interest expense lapping recognition of a loss on extinguishment of the 2023 SVB convertible term loan in the prior period;
- Net loss was ($39.8) million vs. ($29.8) million or ($1.24) and ($1.50) per share, respectively.

As of December 31st, 2024, cash and equivalents totaled $34.49 million. This amount compares to a $15.5 million balance in cash and equivalents held at the end of 2023 with the increase due to the February 2024 equity raise. 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 new drug application (NDA). Cash used in operations during 2024 was ($29.8) million versus ($24.5) million in the prior year period. Management estimates that the company has sufficient cash to support operations until 3Q:25.

Commercial Launch Preparation

Achieve is developing a commercialization plan which will target the most receptive providers and patients that have the highest likelihood of recognizing the value provided by cytisinicline. During the 2024 earnings call, management provided a laundry list of efforts that are underway. The label is being developed, packaging is being finalized and the team is in the process of selecting its third-party logistics partner. Launch readiness activities are centered on awareness, access and availability. Achieve will soon engage with payors to discuss pricing, payment, contract and access requirements. A targeted digital campaign will be the primary channel for the commercialization team which will identify high-volume varenicline subscribers and highly motivated quitters.

Exhibit I – Precise Targeting of High-Volume Prescribers & Engaged Quitters



Source: Achieve February 2025 Corporate Presentation

Vaping Indication

Last year, Achieve requested a Type B end of Phase II (EoP2) meeting with the FDA for the vaping indication where the two parties began discussions for designing a pivotal trial. Achieve obtained FDA agreement on the proposed single Phase III study design for cytisinicline treatment in vaping cessation. The agreement further outlined the additional requirements for submitting a supplemental new drug application (sNDA) to expand cytisinicline's label to include treatment for vaping cessation.

The EoP2 meeting solidified the proposed Phase III study design, including the inclusion/exclusion criteria, primary and secondary efficacy objectives, definition of vaping abstinence with biochemical verification, and other overall study assessments. The FDA agreed that one well-controlled Phase III trial (ORCA-V2), in addition to Achieve's completed Phase 2 ORCA-V1 trial, would be acceptable for a vaping cessation indication as an sNDA. Additionally, the FDA agreed that the company's safety exposure data from the ongoing ORCA-OL study would be adequate for the vaping cessation label expansion.

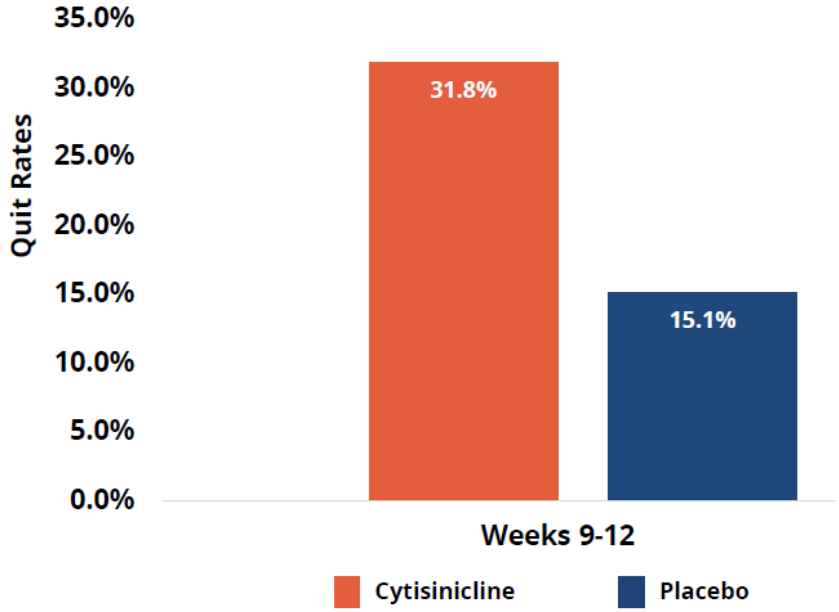
Vaping Trial Design:

- Study population will be adults dependent on nicotine e-cigarettes and who have failed previous attempts to stop;
- 3 mg of cytisinicline will be dosed 3x per day for 12 weeks vs. placebo in 800 vapers (but not smokers) with each group receiving behavioral support;
- The primary endpoint is abstinence for the last four weeks of treatment and the secondary endpoint is continuous vaping cessation for weeks 9 to 24;
- Safety, adherence to study treatment, and other patient-reported outcomes on vaping urges and craving symptoms will also be measured.

Last July, Achieve announced that the FDA had granted Breakthrough Therapy status to cytisinicline for the treatment of e-cigarette or vaping nicotine dependence. The designation is designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that they may demonstrate substantial improvement over available therapy based upon a clinically significant endpoint. The status provides for expedited development where Achieve can receive intensive guidance on drug development, have close contact with the senior managers and review staff at the agency, participate in rolling review and potentially be eligible for priority review, which can shave some time off of the approval process.

Management expects to leverage this expedited status to obtain a label that allows for adolescent use as this demographic uses vaping products at a much higher rate than older individuals. Additionally, in the December press release, it reiterated its 3Q:25 target for starting the single required Phase III vaping trial.

Exhibit II – Phase II Vaping Trial Quit Rates (3 mg TID vs Placebo)



Source: Achieve February 2025 Corporate Presentation

ORCA-OL Safety Trial

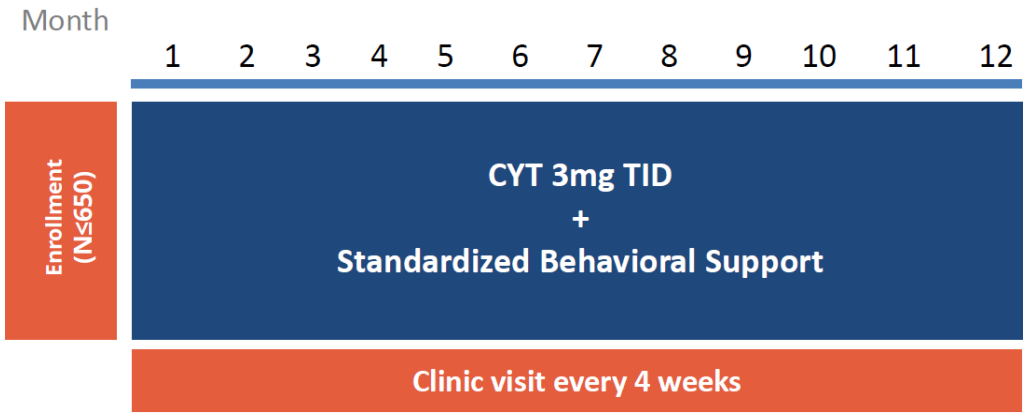
Achieve began 2025 with good news announcing that 300 participants had completed six months of treatment in the Ongoing Research of Cytisinicline for Addiction Program, Open Label (ORCA-OL) trial. The Data Safety Monitoring Committee (DSMC) identified no safety concerns as of this milestone allowing registrational filing with the FDA. A second DSMC review memorialized in a February 10th press release also did not identify any unexpected treatment-related adverse events and found that the subjects' adherence to their treatment regimen was "excellent." Reaching this juncture places Achieve on track to submit its new drug application (NDA) to the FDA in 2Q:25. Safety data for the final 100 patients should be available by June. Following analysis, it will be compiled and submitted along with the NDA on a rolling basis.

ORCA-OL Background
The ORCA-OL trial launched in May 2024 and began with rapid enrollment, high screening success rates and a single digit dropout rate. More than 650 subjects were enrolled with about two thirds having already completed six or twelve weeks of treatment in previous ORCA trials when they started ORCA-OL. 29 sites actively enrolled for the trial with the objective of obtaining six months of safety data from 300 of these individuals in support of the anticipated filing of the NDA in 1H:25. On October 10th, Achieve completed enrollment with 479 participants. The company also passed its first Data Safety Monitoring Committee (DSMC) review for the trial, which concluded that there were no safety concerns.

The ORCA OL trial arose from the FDA's desire for additional long-term cytisinicline exposure data to adequately assess safety risk. Despite an initial anticipated treatment duration of six to twelve weeks, cytisinicline could be used for chronic, repeat or intermittent use if a patient relapses. With this possibility guiding its interactions with drug sponsors, the FDA and Achieve reached an agreement that a single, open-label study evaluating long-term safety exposure of cytisinicline will meet the safety requirement. Details of the arrangement were provided in a February 29th press release and are described further below.

The completed study will include safety data on at least 300 subjects that have received cumulative cytisinicline treatment for six months. After the 300 subjects complete six months of treatment, Achieve expects a three-month turnaround to collect the data, analyze it and incorporate the safety data into the safety summary document for the new drug application (NDA). This suggests an NDA submission in the May timeframe. Generally, it takes about one year from NDA submission to receive a response from the FDA. While the FDA is reviewing the package, Achieve will submit the final 100 patients with one year of data (we estimate) somewhere around November 2025.

Exhibit III – ORCA-OL Study Design



Source: Achieve Life Sciences July 2024 Corporate Presentation

New Faces at Achieve

In early December, Achieve appointed Mark Oki as Chief Financial Officer who will take the financial reins of the company as it moves towards regulatory submission and commercialization of cytisinicline. He will be responsible for the company's financial strategy and operations, including accounting, investor relations, information technology, legal and other key administrative functions. Mark has a long history as CFO, serving in this role at Aytu BioPharma, Vivus and Alexza Pharmaceuticals during his executive career. Starting at Deloitte & Touche, Mark Oki offers over 25 years of professional experience. He is an alumnus of San Jose State University with a business administration degree in accounting.

Exhibit IV – Chief Financial Officer, Mark Oki

Mark Oki

Chief Financial Officer

Over 25 years of financial leadership experience in the biotechnology and pharmaceutical industries, having served as CFO at companies like Aytu BioPharma, Vivus LLC (formerly Vivus, Inc.), and Alexza Pharmaceuticals.

Source: Achieve February 2025 Corporate Presentation

Achieve also adds to its board, appointing two experienced healthcare executives who replaced a previous director, Dr. Vaughn Himes. Dr. Himes, who had previously served at Seagen, retired. The January 10th announcement introduced Kristen B. Slaoui, Ph.D. and Nancy R. Phelan to investors and stakeholders.

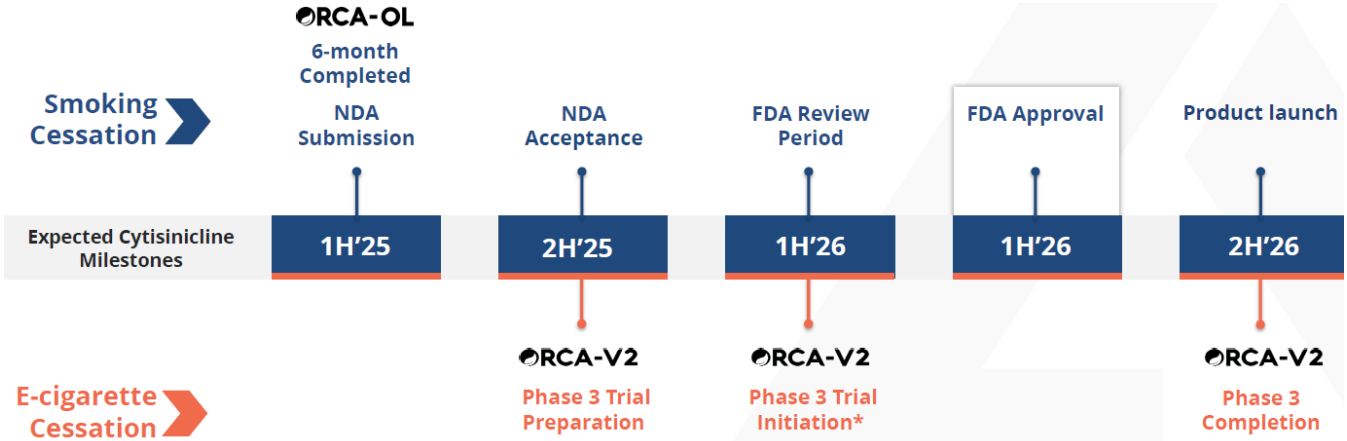
Dr. Kristen Slaoui, has served as the Chief Corporate Development Officer at Galderma, a leading global dermatology company, since 2020, and serves on the board of directors of Kinaset Therapeutics and the board of advisors of Advancing Innovation in Dermatology. She has led the effort to complete a number of significant transactions, including the 2021 acquisition of Alastin Skincare. Prior to joining Galderma, Dr. Slaoui spent 20 years at GSK, contributing to groundbreaking pulmonary disease research and the development of several approved medicines and held various roles of increasing seniority in Business Development teams, executing over $30 billion in deals, including major acquisitions like Stiefel Laboratories and Tesaro. She holds a B.S. in biology and classical studies from Gettysburg College, a Ph.D. in physiology from The Johns Hopkins University Bloomberg School of Public Health and completed a post-doctoral fellowship in pharmacology at the University of Washington School of Medicine.

Nancy R. Phelan, brings over 25 years of executive leadership in the biopharma and service industries. Nancy serves as Senior Vice President at Trinity Life Sciences and on the boards of directors of Medexus Pharmaceuticals and FemmePharma. At Trinity Life Sciences, Nancy has launched and heads a new Center of Excellence dedicated to data and analytics driven digital transformation and innovative customer engagement solutions with a focus on cutting-edge technology and AI. Nancy's extensive pharmaceutical business model transformation and customer engagement commercialization expertise spans prescription and over-the-counter drugs. Prior to Trinity Life Sciences, Nancy was a Senior Vice President, Omnichannel Activation at Indegene and also held leadership roles at global pharmaceutical companies Novartis, Bristol Myers Squibb and Pfizer. Throughout her career, Nancy has led commercialization strategies and launches which have generated significant revenue growth and market expansion. She has received many industry awards including MM+M Woman of Distinction, DTC Hall of Fame, PM 360 ELITE Digital Crusader, Working Mother Cover Mom and Pharmaceutical Executive 40 under 40. Ms. Phelan holds a B.A. with Honors in history from Franklin & Marshall College.

Milestones

- Launch of ORCA-OL trial – May 2024
- Addition to the Russell 3000 and Microcap Indices – July 2024
- Refinancing of SVB loan – July 2024
- Grant of Breakthrough Therapy Designation for vaping indication – July 2024
- Appointment of Dr. Mark Rubinstein as Head of Medical Affairs – October 2024
- ORCA OL enrollment completed – October 2024
- Promotion of Jaime Xinos to Chief Commercial Officer – October 2024
- Dr. Cindy Jacobs, Chief Medical Officer, speaks at FDA/NIH Smoking Cessation Meeting – October 2024
- End of Phase II meeting with FDA to determine Phase III vaping cessation trial design – 2H:24
- 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
- Submission of new drug application (NDA) – 2Q:25
- Data from 100 patients with twelve months exposure to cytisinicline – mid-2025
- Launch of Phase III vaping trial – 3Q:25
- FDA target action date for cytisinicline NDA – 1H:26
- Launch of cytisinicline – 3Q:26

Exhibit V – Achieve Development Timeline



Source: Achieve February 2025 Corporate Presentation

Summary

Achieve is continuing to develop its NDA having completed the compilation of Phase I, II and III study reports, finalizing the summary of efficacy documents and soon moving on to the summary of safety documents. The Chemistry, Manufacturing and Controls (CMC) section is near completion. The team is on track for a 2Q:25 submission. Following the turnover of the NDA to the FDA, Achieve will turn to analyzing the data from the last 100 patients in the ORCA-OL safety trial and prepare for the pivotal vaping trial. Pre-commercialization activities are ongoing and the team is narrowing its focus to the most likely providers and patients that will be receptive to and benefit from cytisinicline. Achieve has outlined its timeline and we anticipate FDA approval some time in 2Q:26 with commercialization and first sales to begin in 2H:26. 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.

PROJECTED FINANCIALS

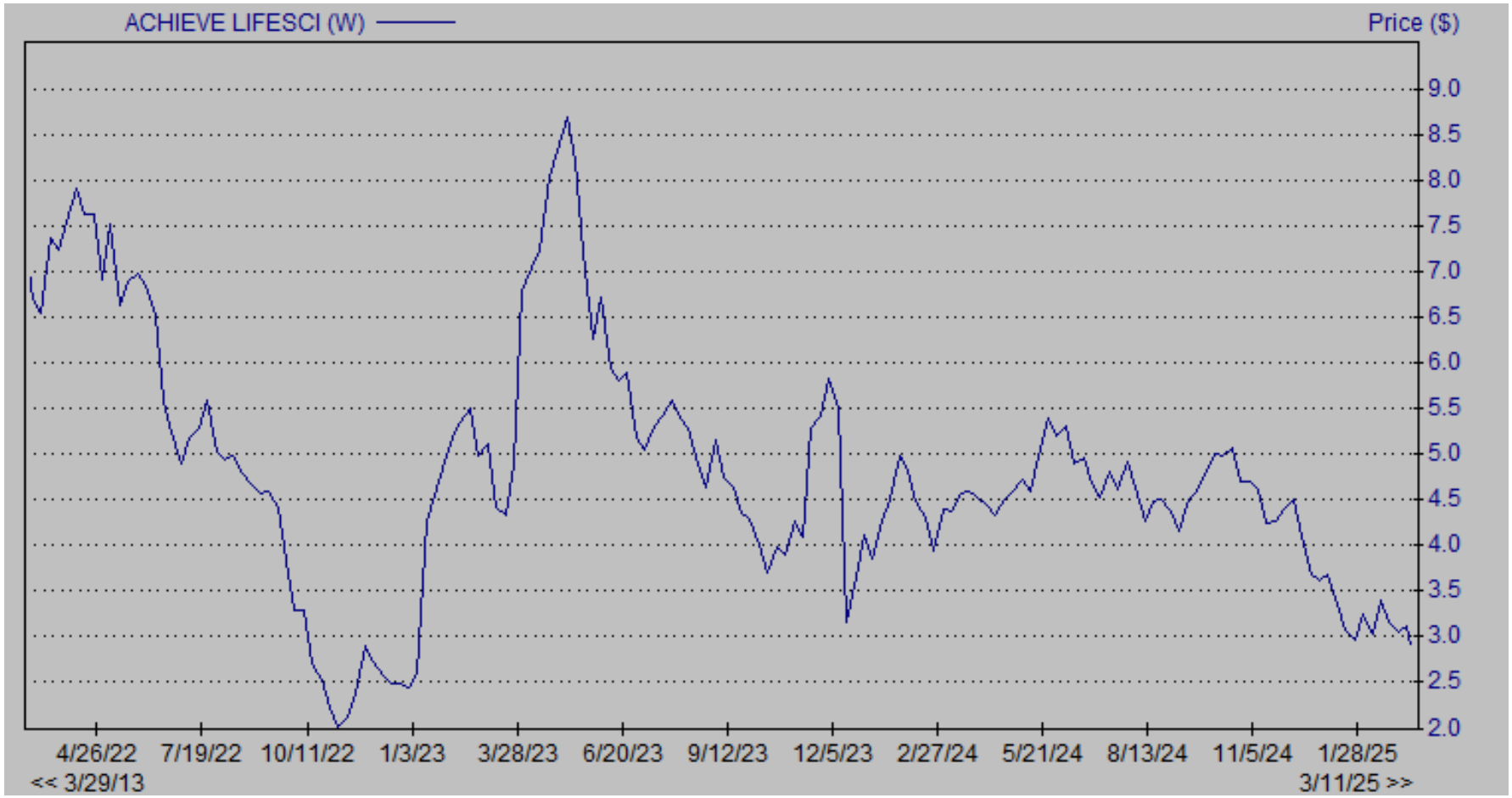
Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 A	2024 A	2025 E	2026 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$50.2**
Growth	-					-	-	-
R&D	$15.8	$2.8	$5.1	$7.6	$7.3	$22.8	$11.0	$5.0
G&A	$11.4	$3.2	$3.3	$4.9	$4.9	$16.3	$28.0	$29.0
Sales Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$6.1	$11.4
Operating Income	($27.3)	($6.0)	($8.4)	($12.5)	($12.2)	($39.1)	($45.1)	$4.7
Operating Margin								*9.4%*
Interest Income	($2.0)	($0.4)	$0.0	$0.0	$0.6	$0.2	$0.0	$0.0
Total Other Income	($0.5)	($0.1)	($0.0)	($0.0)	($0.8)	($0.9)	$0.0	$0.0
Pre-Tax Income	($29.8)	($6.5)	($8.5)	($12.5)	($12.4)	($39.8)	($45.1)	$4.7
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	($29.8)	($6.5)	($8.5)	($12.5)	($12.4)	($39.8)	($45.1)	$4.7
Reported EPS	**($1.50)**	**($0.26)**	**($0.25)**	**($0.36)**	**($0.36)**	**($1.24)**	**($0.93)**	**$0.08**
YOY Growth								
Shares Outstanding	19.8	25.0	34.3	34.4	34.5	32.1	48.7	56.7

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

HISTORICAL STOCK PRICE

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



[1] Source: Zacks Research System

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