

Achieve Life Sciences, Inc.

(ACHV: NASDAQ)

ACHV: Second Quarter Results

We employ a DCF model and a 15% discount rate to generate our valuation. Our model applies an 80% probability of eventual cytisinicline sales based on historical approval rates based on successful Phase III trials and new drug application acceptance rates. Our valuation includes geographic contributions only from the United States.

Current Price (8/7/2025) **\$2.64**
Valuation \$25.00

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 and has submitted its NDA as of June 2025. Achieve is now conducting pre-commercialization activities.

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 **5.31**
 52-Week Low **1.84**
 One-Year Return (%) **-43.1**
 Beta **1.6**
 Average Daily Volume (sh) **910,553**

Shares Outstanding (mil) **51.1**
 Market Capitalization (\$mil) **134.9**
 Short Interest Ratio (days) **1.4**
 Institutional Ownership (%) **34.2**
 Insider Ownership (%) **3.7**

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	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2024	\$0.0 A				
2025	\$0.0 A	\$0.0 A	\$0.0 E	\$0.0 E	\$0.0 E
2026					\$20.1 E
2027					\$104 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2024	-\$0.26 A	-\$0.25 A	-\$0.36 A	-\$0.36 A	-\$1.24 A
2025	-\$0.37 A	-\$0.37 A	-\$0.25 E	-\$0.22 E	-\$1.15 E
2026					-\$1.07 E
2027					\$0.69 E

WHAT'S NEW

Achieve Life Sciences, Inc. (NASDAQ: ACHV) reported its second quarter 2025 results and highlighted several milestones achieved since the last quarterly update. This includes forging a partnership with Omnicom for launching cytisinicline, submitting the New Drug Application (NDA), generating necessary safety exposure data for the NDA and publishing ORCA-3 results in the Journal of the American Medical Association (JAMA).

During its second quarter earnings conference call, management elaborated on the ORCA-OL trial and commercialization preparation efforts. As a follow up to the trial, a survey was given to participants who reported very high levels of satisfaction and success with cytisinicline. On the commercialization front, new members have been added to the team to help with the initiative emphasizing availability, access and awareness. Looking ahead, management expects to have the NDA submission accepted by September and to remit ORCA-OL safety data in October.

Financial and Operational Results

Achieve's second 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 2Q:25. Operating expense was \$12.6 million producing a net loss of (\$12.7) million or (\$0.37) per share. For the quarter ending June 30th, 2025 and versus the same comparable prior year quarter:

- Research & development expense totaled \$6.7 million, up 31% from \$5.1 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 (\$155,000) vs. (\$30,000) as interest income offset interest expense and minor miscellaneous items including other expense and change in fair value comprised the remainder;
- Net loss was (\$12.7) million vs. (\$8.5) million or (\$0.37) and (\$0.25) per share, respectively.

As of June 30th, 2025, cash and equivalents totaled \$55.4 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. In July 2024, 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, which we expect in September. Cash used in operations during 2Q:25 was (\$9.1) million versus (\$4.9) million in the same prior year period. On the last day of the second quarter, Achieve closed a capital raise which generated net proceeds of \$41.3 million. Following the end of the reporting period, on July 25th, 2025, the underwriters exercised their option to sell 1.4 million additional shares at \$3.00. We estimate this generated just under \$4 million in net proceeds that add to the June 30 cash balance.

Public Offering

On June 30th, 2025 Achieve [closed](#) its \$45 million capital raise. 15 million shares were issued at \$3.00, each of which included an attached warrant exercisable at \$3.00 per share. An additional 1,766,666 warrants were issued upon the partial exercise by the underwriters of their option to purchase additional shares, bringing total issued warrants to approximately 16.8 million. Net proceeds from the capital raise are estimated to be \$41.3 million as disclosed in the June 27th [Form 8-K](#) filing. On July 25th, 2025, the underwriters exercised their option to purchase an additional 1,419,896 shares at \$3.00 per share.

NDA Submission

Achieve announced its NDA submission of cytisinicline for smoking cessation in a June 26th [press release](#). The company conducted two Phase III studies, an open label safety study and other studies that evaluated over 2,000 participants with the results demonstrating the safety, efficacy and tolerability of cytisinicline. As per management guidance, we expect to see acceptance of the NDA in September and one-year ORCA-OL safety data to be shared with the agency in October.

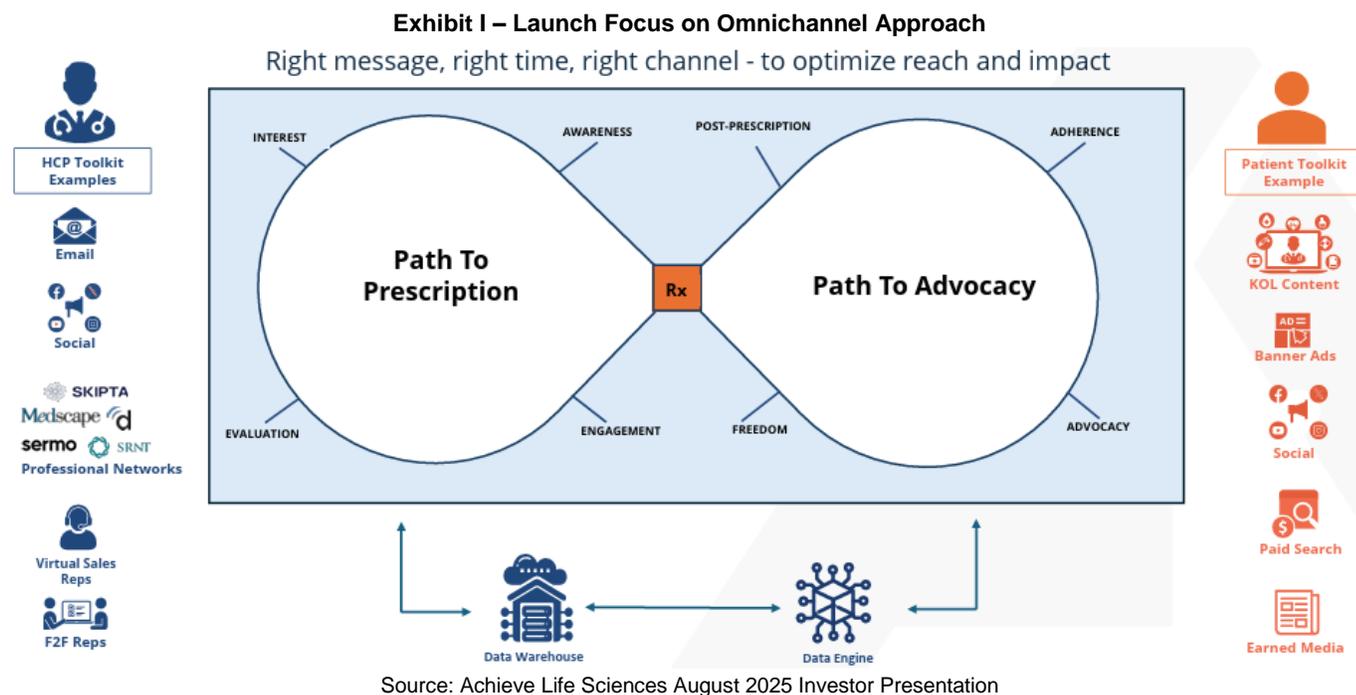
Commercialization Partnership

Since the first quarter update, Achieve has made further progress advancing its commercialization efforts. During its earnings calls, the company has outlined its commercialization strategy and is now partnering with [Omnicom Group](#) to execute the plan. Omnicom Group provides brand and advertising services to thousands of clients globally and is one of the world's largest advertising and marketing services companies.

Achieve will work with Omnicom subsidiary Credera, which is focused on digital transformation services. Credera combines consulting, artificial intelligence (AI) and technology expertise to build consumer technology platforms, integrate marketing technology systems and provide strategic consulting services. It will help Achieve to precisely target and engage healthcare professionals and patients through optimization of channel performance and acceleration of meaningful engagement. The team executing the initiative will include Goodby, Silverstein & Partners, DDB Health, and Ketchum Health which are health care-focused subsidiaries of the Omnicom marketing group.

The various subsidiaries will provide expertise in consumer brand development, medical education and strategic public relations and communications, applying industry insights to support cytisinicline launch. In the Achieve partnership, Ketchum Health brings public relations and communications expertise, while Credera handles technology, Goodby Silverstein provides creative advertising, and DDB Health focuses on healthcare marketing. The partnership will use generative AI, predictive analytics and social listening to enhance targeting and personalization. Using a comprehensive approach, it will also employ healthcare applications, pharmacies and data providers to expand the reach and depth of insights.

Omnicom has worked as media agency, digital and brand experience for other pharmaceutical and biotechnology clients including established firms such as AbbVie, AstraZeneca, Novartis and Moderna among others. Achieve will be the first small company that Omnicom has supported in commercializing a newly approved drug. Therefore, Omnicom will take on a broader strategic role than in its past partnerships. The Omnicom team will help communicate the optimal message to the provider and patient and monitor its effectiveness in real time. This will allow for rapid course corrections and focus on high value activities.



Achieve has identified several target groups for its marketing efforts that are stratified by age, social media use and other demographic data. It was able to identify these groups based on subject experiences in the company's many clinical trials. We anticipate that the structure of Achieve's internal marketing team will be heavily tilted toward supporting the digital campaign with contract representatives available for in-person physician meetings when appropriate.

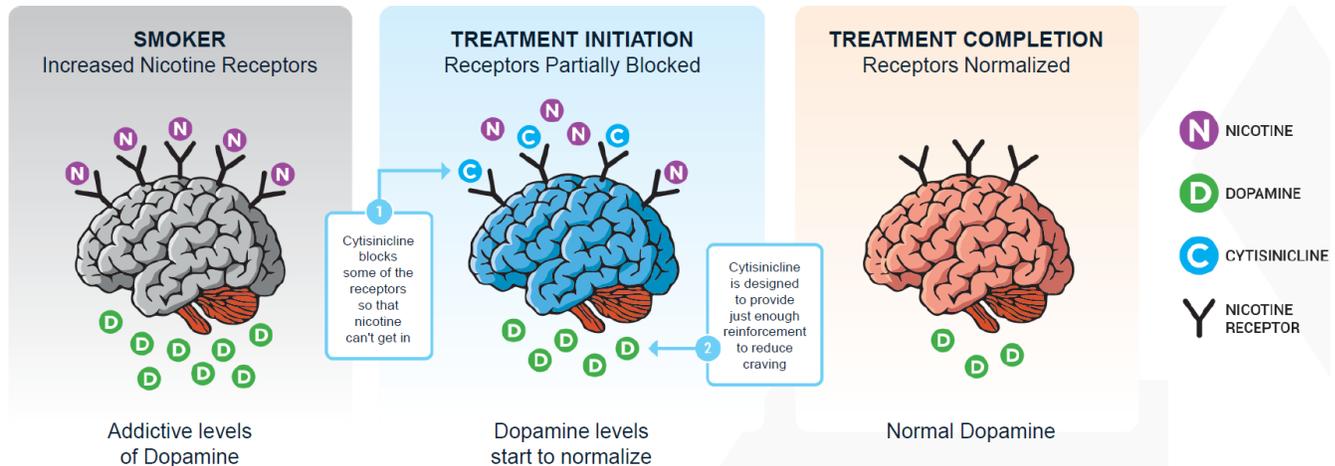
During the second quarter call, Chief Commercial Officer Jamie Xinon further explained Achieve's strategy that revolves around three imperatives: availability, access and awareness. Availability seeks to ensure product readiness

at launch. In this effort, the company has contracted with a third-party logistics provider and has begun a home state licensing application that will trigger applications in additional states. On the access front, a new Vice President of Market Access has joined the team leading up the effort to conduct extensive payor research. Among other objectives, awareness will reframe nicotine dependence as a medical condition rather than a lifestyle choice that can be addressed with cytisinicline. In reaching out to prospects, two groups will be initially emphasized: motivated patients ready to quit and providers that prescribe high volumes of smoking cessation therapies. The approach will be constantly monitored and refined to optimize the effort. Awareness will seek to meet each stakeholder with the right message at the right time.

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 II – Cytisinicline’s Dual-Acting Mechanism of Action



Source: Achieve Life Sciences August 2025 Investor Presentation

ORCA-OL Safety Trial

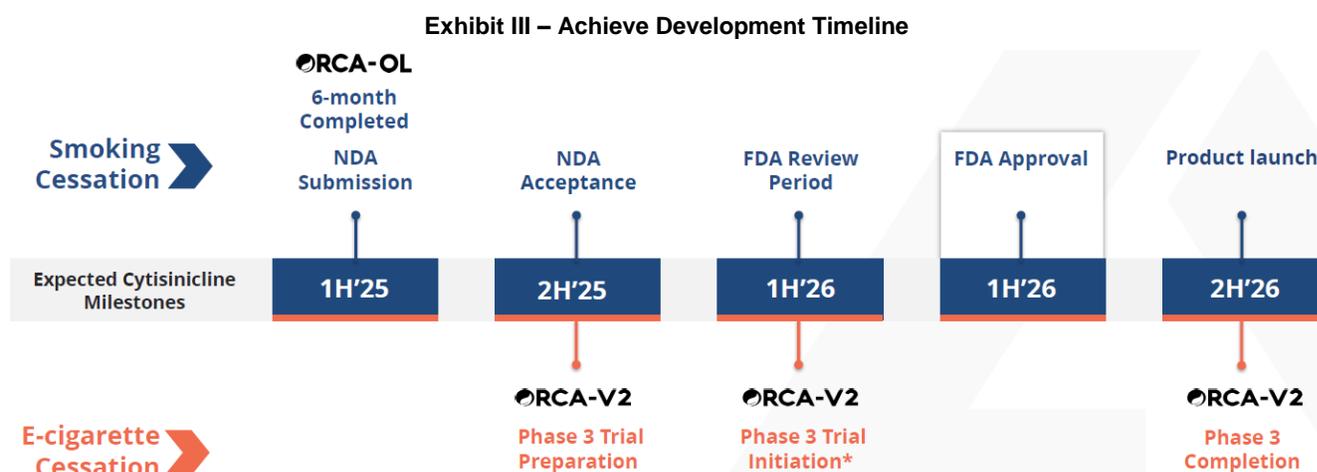
Achieve began 2025 by [announcing](#) that 300 participants had completed six months of treatment in the Ongoing Research of Cytisinicline for Addiction Program, Open Label (ORCA-OL) trial. The Data Safety Monitoring Committee (DSMC) identified no safety concerns as of this milestone allowing registrational filing with the FDA. As of August 2025, 290 individuals have completed one year of cytisinicline treatment. After completion, participants were given a survey and of the ~116 that have responded, 99% would recommend cytisinicline to friends or others and 98% believe that cytisinicline was the reason they were able to quit. Few reported unmanageable side effects. 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 will soon complete the one-year safety data package and will submit it to the FDA by the 120-day safety review milestone expected in October. Achieve will significantly exceed the 100-patient minimum required for one year of safety observations and could see as many as 300 patients with one year of exposure. Since one of the secondary endpoints is efficacy, this study should be able to show a wealth of data that can help providers use cytisinicline more effectively especially in chronic areas of disease such as Chronic Obstructive Pulmonary Disease (COPD) and cardiology.

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

Milestones

- 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 2025
- [Attendance](#) at Barclays Healthcare Conference, Miami – March 2025
- Selection of 3rd party logistics partner – 2Q:25
- NDA Submission – 2Q:25
- BTIG Virtual Biotechnology Conference [attendance](#) – July 2025
- Anticipated acceptance of NDA by FDA – September 2025
- FDA data submission from patients with twelve months of exposure to cytisinicline – 4Q:25
- Launch of Phase III vaping trial – 1H:26
- FDA target action date for cytisinicline NDA – 1H:26
- Launch of cytisinicline – Late 2026



Source: Achieve August 2025 Corporate Presentation

Summary

Achieve has submitted its NDA and continues to ramp up its commercialization preparations. The company also raised additional capital on the back of the FDA submission, increasing its treasure chest by approximately \$45 million including the underwriter purchase option. These funds will support the continued efforts to prepare cytisinicline for commercialization and fund the company through the regulatory process. Teaming up with Omnicom will give Achieve access to one of the largest global media, marketing and corporate communications companies in the world and will help expand Achieve's reach with cytisinicline and aid in the execution of their commercialization strategy.

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.

PROJECTED FINANCIALS

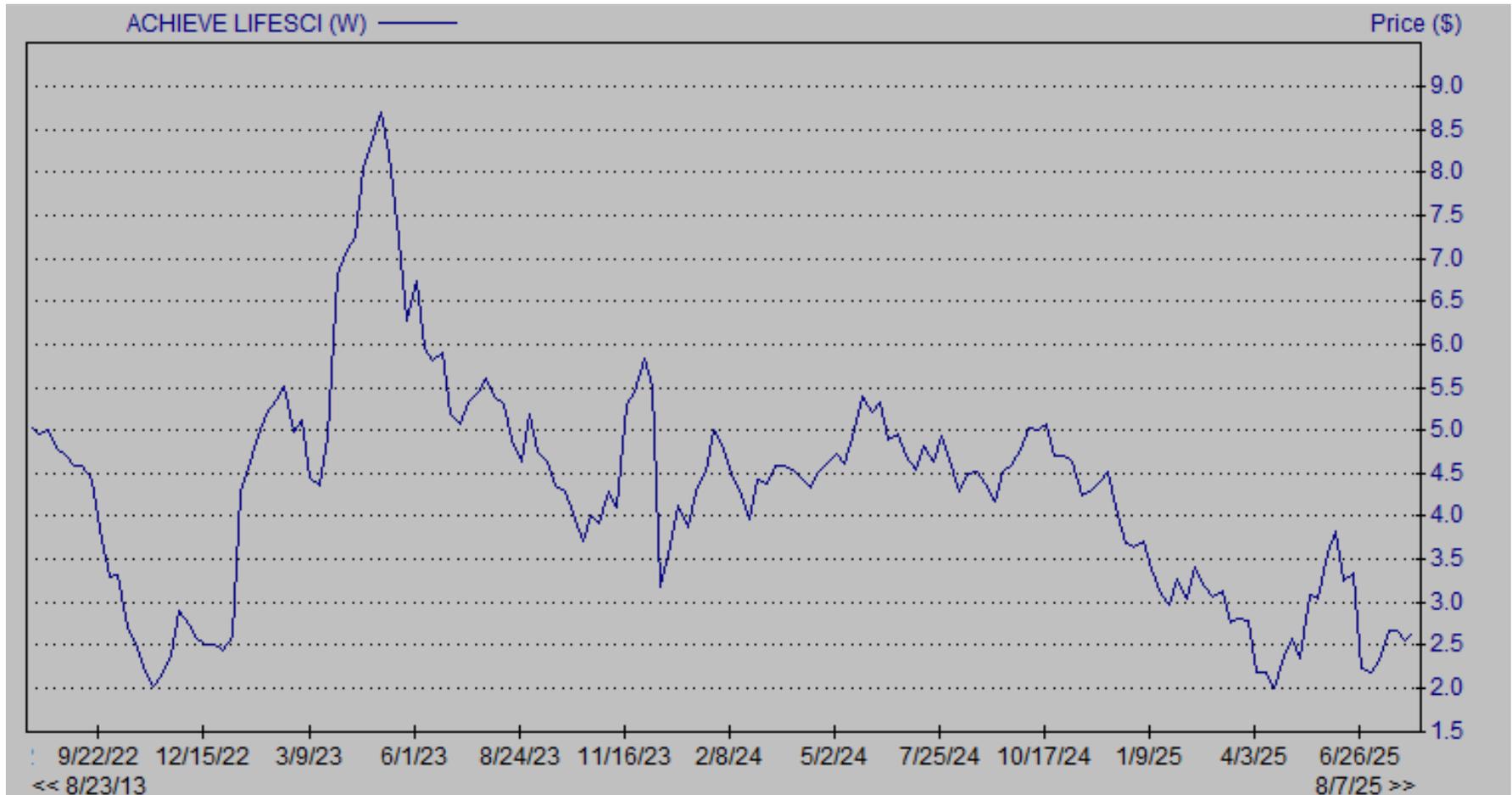
Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2024 A	Q1 A	Q2 A	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	\$6.7	\$3.5	\$1.8	\$19.1	\$29.0	\$0.0
G&A	\$16.3	\$5.8	\$5.9	\$6.0	\$6.6	\$24.3	\$29.0	\$29.6
S&M	\$0.0	\$0.0	\$0.0	\$3.4	\$5.0	\$8.4	\$26.1	\$31.5
Operating Income	(\$39.1)	(\$12.9)	(\$12.6)	(\$12.9)	(\$13.4)	(\$51.8)	(\$64.1)	\$42.6
<i>Operating Margin</i>							-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)	(\$0.3)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Pre-Tax Income	(\$39.8)	(\$12.8)	(\$12.7)	(\$12.8)	(\$12.7)	(\$51.8)	(\$64.1)	\$42.6
Taxes & Other	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$39.8)	(\$12.9)	(\$12.7)	(\$12.8)	(\$12.7)	(\$51.8)	(\$64.1)	\$42.6
Reported EPS	(\$1.24)	(\$0.37)	(\$0.37)	(\$0.25)	(\$0.22)	(\$1.15)	(\$1.07)	\$0.69
<i>YOY Growth</i>								
Shares Outstanding	32.1	34.7	34.7	51.1	59.0	44.9	59.7	62.0

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

HISTORICAL STOCK PRICE

Achieve Life Sciences, Inc. – Stock Price Chart²



² Source: Zacks Research System

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