

Achieve Life Sciences, Inc.

(ACHV: NASDAQ)

ACHV: 2025 Results

Our valuation approach employs a DCF model and a 15% discount rate. We apply an 85% probability of eventual cytidine sales based on historical approval rates. The estimate is based on historical success rates for Phase III trials and new drug application acceptance. Our valuation includes geographic contributions only from the United States.

Current Price (3/23/2026) **\$4.05**
Valuation \$20.00

OUTLOOK

Achieve Life Sciences is developing cytidine for use as a smoking cessation treatment in the United States and rest of world. Pivotal studies have been completed with safety & efficacy results exceeding expectations. Achieve is now awaiting its target action date of June 20th, 2026 while preparing for commercialization. It has hired Omnicom and its family of businesses to help execute its plan.

Existing cessation products provide limited effectiveness and produce unpleasant side effects including nausea, vivid dreams, insomnia & gastrointestinal issues. Cytidine 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 from 25 to 30 million smokers in the US and over 1 billion globally, providing a substantial population demanding an improved smoking cessation product. We anticipate a 1H:27 commercialization of cytidine.

A pivotal vaping trial is planned for 2026. The vaping indication has been awarded a CNPV, which will accelerate the approval timeline but must be used within two years of grant.

SUMMARY DATA

52-Week High **6.03**
 52-Week Low **1.84**
 One-Year Return (%) **44.13**
 Beta **1.8**
 Average Daily Volume (sh) **576,142**

Shares Outstanding (mil) **53.2**
 Market Capitalization (\$mil) **215.4**
 Short Interest Ratio (days) **11.8**
 Institutional Ownership (%) **46.9**
 Insider Ownership (%) **4.4**

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				
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	-\$0.28 A	-\$0.28 A	-\$1.25 A
2026					-\$1.40 E
2027					\$0.65 E

WHAT'S NEW

Achieve Life Sciences, Inc. (NASDAQ: ACHV) reported 2025 results following the submission of a new drug application (NDA) to the FDA and the assignment of cytisinicline's Prescription Drug User Fee Act (PDUFA) date of June 20th, 2026. While the FDA reviews the application, Achieve has been hard at work on pre-commercialization activities working with Omnicom to support the commercial launch of cytisinicline. Since the company's previous quarterly update in November, Dr. Mark Rubinstein has been promoted to Chief Medical Officer, management held meetings during the JP Morgan Healthcare conference in January and team members presented data from the pivotal and safety trials at the Society for Research on Nicotine & Tobacco (SRNT) 2026 Annual Meeting. In its earnings release Achieve announced that it will be working with the domestic manufacturer Adare Pharma to provide cytisinicline drug product to support an anticipated 1H:27 product launch.

Financial and Operational Results

Achieve's 2025 financial and operational results were detailed in a [press release](#), [Form 10-K](#) filing and a [webcast](#) which provided analysts the opportunity to ask questions. No revenues were reported in 2025. Operating expense was \$54.9 million producing a net loss of (\$54.7) million or (\$1.25) per share. For the year ending December 31st, 2025 versus the prior year:

- Research & development expense totaled \$23.0 million, up 1% from \$22.8 million, due to higher employee costs from increased headcount and higher manufacturing and supply chain costs associated with commercial launch preparation, including purchase of raw cytisinicline inventory expenses prior to regulatory approval. This was partially offset by lower clinical trial costs associated with the wind down of the ORCA-OL trial, which was completed last year;
- General & administrative expense was \$31.9 million, up 96% from \$16.3 million on higher employee expenses and commercial launch preparation;
- Net interest income was \$0.7 million vs. \$0.2 million as interest income offset interest expense on higher cash balances;
- Other expense of \$0.4 million compares to \$0.9 million. The amount is related to change in fair value of contingent consideration and other expense;
- Net loss was \$54.7 million vs. \$39.8 million or \$1.25 and \$1.24 per share, respectively.

As of December 31st, 2025, cash and equivalents totaled \$36.4 million. This compares to a \$34.4 million balance held at the end of 2024. At year end, Achieve carried convertible debt of \$14.9 million on the balance sheet which includes an additional \$5 million drawn down in October 2025 upon achieving its milestone of NDA acceptance. Cash used in operations during 2025 was \$49.5 million versus \$29.8 million in the same prior year period.

NDA Submission and Acceptance

Achieve announced its NDA submission of cytisinicline for smoking cessation in a June 26th [press release](#). On September 3rd, the company [reported](#) FDA acceptance of its NDA and the assignment of a June 20th, 2026 Prescription Drug User Fee Act (PDUFA) date. Cytisinicline completed two Phase III studies, an open label safety study and other studies that evaluated over 2,000 participants with the results demonstrating its safety, efficacy and tolerability. In November, the final cohort of 12-month safety data was submitted to the FDA, providing all of the expected data submission necessary for the submission to be complete.

SRNT Presentation

Achieve [presented](#) new data at the Society for Research on Nicotine & Tobacco (SRNT) 2026 Annual Meeting, held from March 4-7 in Baltimore, Maryland. Information was presented at two sessions drawing from participants in the ORCA-OL and the more than 1,600 participants in the ORCA-2 and ORCA-3 studies. Titles of the sessions and conclusions are included below.

- Cytisinicline in Adult Smokers: Post-Trial Survey from ORCA-OL
 - Many individuals do not complete a smoking cessation course of therapy due to side effects and patient experience is important to success
 - Participants reported better physical health while taking cytidinicline including improved breathing, increased stamina and greater vitality
 - Participants were satisfied with cytidinicline reporting that the urge to smoke had lessened, and fewer psychological cravings
 - Cytisinicline was well tolerated even with up to one year of use with no new safety signals during the open label phase
- Efficacy of Cytisinicline for Smoking Cessation in Adults with and without Multiple Prior Quit Attempts or Prior Pharmacotherapy Use: Pooled Analysis of Two Phase 3 Trials
 - The presentation concluded that cytidinicline was effective and well-tolerated regardless of participants' prior use of smoking cessation medications or number of previous quit attempts
 - If approved in the US, cytidinicline will offer a new quit option for patients, including those who have failed other medications
 - Cytisinicline was consistent across regimens with benefits observed for both the six- and twelve-week treatment courses, although the twelve-week course provided improved long-term outcomes

Thorax Publication

Data from Achieve's ORCA trials were published in the journal Thorax under the title [Cytisinicline for smoking cessation in individuals with self-reported COPD: a post hoc analysis of the ORCA-2 and ORCA-3 trials](#). As indicated by the heading, the review examined a subset of patients with Chronic Obstructive Pulmonary Disease (COPD) who were enrolled in Achieve's cytidinicline trials. The article notes that COPD patients suffer more from the negative effects of smoking than their non-COPD counterparts and that this segment of the smoking population would benefit more from smoking cessation than other groups without such comorbidities. The article observes that while COPD patients try to quit at a higher rate than other smokers, they are less likely to succeed. The journal publication also notes that existing approved smoking cessation products have many associated side effects that lead to high rates of discontinuation.

For long term followers of Achieve, the results shared in the paper were not surprising. Quit rates were substantially higher for patients using cytidinicline. When examining the [COPD subset](#), the relative benefit of cytidinicline was greater in the COPD arm than it was for the non-COPD arm at six weeks of cytidinicline treatment. At 12 weeks the difference between the active and control arm for the non-COPD and COPD subgroups was less pronounced. However, when the two arms were examined at 12 weeks using the Odds Ratio, the COPD arm was slightly ahead at 5.3 vs. 5.2. See the link for a [graphic representation](#). The authors concluded that "Cytisinicline's low side effect profile and high treatment adherence make it an appealing option for those struggling to quit smoking, potentially lowering medical costs and improving long-term health outcomes."

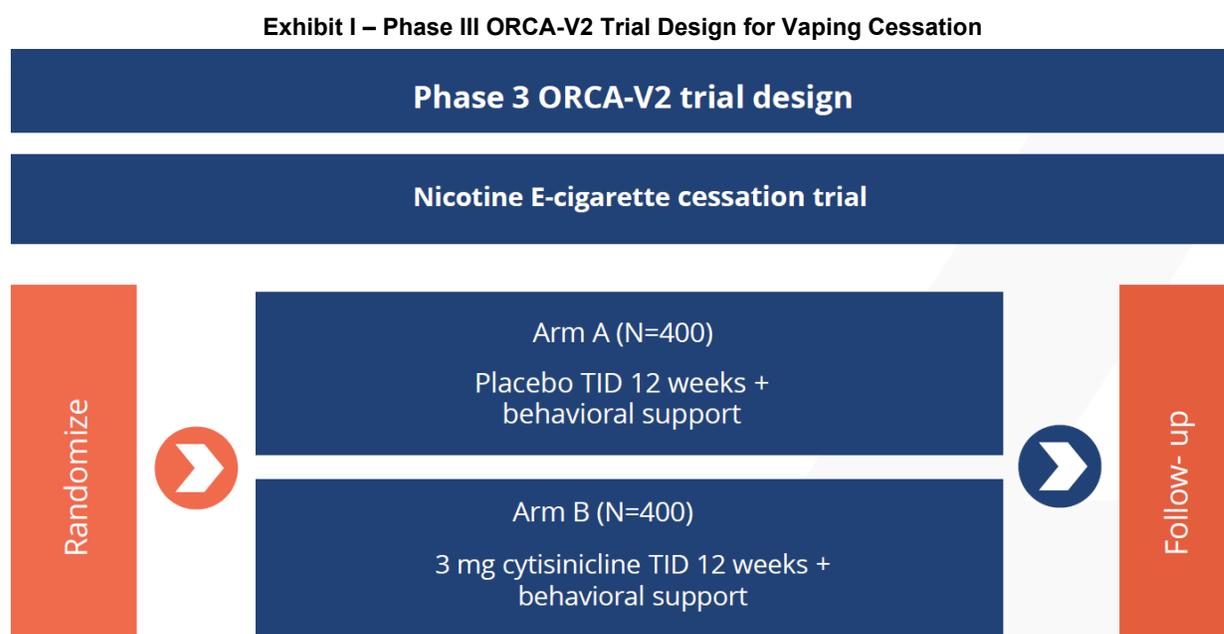
National Priority Voucher

Achieve was [awarded](#) one of nine [National Priority Vouchers](#) for cytidinicline in the nicotine vaping addiction indication. Details of the award were provided in a mid-October [announcement](#). A prospective recipient must offer a product with significant potential to address a major national priority. The priorities include meeting a large unmet medical need, reducing downstream health care utilization, addressing a public health crisis, boosting domestic manufacturing or increasing medication affordability with Most Favored Nation pricing. A drug and indication with a voucher will receive a decision within one to two months following filing of a complete application for a drug or biologic. In addition, sponsors will receive enhanced communications with review staff throughout the development process prior to their final submission and during the review period. The FDA may extend the review time if an application is incomplete, there are manufacturing violations or for other reasons. Achieve has two years to submit a new drug application for a vaping indication in order to take advantage of the voucher.

During the first Trump administration, under Food and Drug Administration (FDA) Commissioner Scott Gottlieb (appointed in 2017), the agency stated intentions to reduce the nicotine yield of combustible cigarettes. The administration also signed the 2020 Federal Budget which raised the smoking age from 18 to 21. The focus on nicotine addiction appears to have, at least in part, carried through to the second administration.

There has been some recent controversy related to the Commissioner's National Priority Voucher (CNPV), as discussed in a recent BioSpace article "[9 Months In, FDA's New Priority Voucher Program Still Clouded With Uncertainty.](#)" Representatives in Congress have claimed that the selection process is shrouded in secrecy and there is lack of transparency with the program. Critics also contend that political appointees rather than scientists are selecting the candidates. The article notes that four products have been approved since the CNPV was announced and one application was rejected. Both management and this analyst do not think the concern will impact Achieve's pursuit of a vaping indication. At the point in time when the vaping indication is expected to be submitted for approval to the FDA, we anticipate cytisinicline will have already been approved for combustible smoking, making it a low-risk process.

Company management is now laying the groundwork for the single, required Phase III vaping trial which will be designated ORCA-V2. Achieve's medical team is selecting sites and identifying principal investigators. The trial is expected to begin in 2026.



Source: Achieve Life Sciences Investor Presentation

Manufacturer Relationships

Achieve raised concerns in its third quarter 10-Q filing regarding Sopharma's ability to pass an FDA pre-approval inspection and has engaged other third-party manufacturers to produce tableted and packaged cytisinicline. In response, Sopharma has alleged that engagement of third-party manufacturers is a breach of the Sopharma License and Supply Agreement. The two parties are discussing a resolution.

Achieve is sourcing its cytisinicline from a supplier in China who is extracting cytisine from the Thermopsis tree. If Achieve is not able to come to an agreement with Sopharma, it plans to source cytisinicline from China, formulate, tablet and package it at partners in India and France, and then have it shipped to the United States for commercialization. Additionally, the company has also disclosed that it has intellectual property rights pending for synthetic cytisinicline. This may play a role in the future and could provide further sourcing flexibility and efficiency.

Due to observations by the FDA related to solid oral dose manufacturing with the manufacturer listed in the NDA and a desire to move production to the United States, Achieve announced that it had partnered with Adare Pharma Solutions to manufacture cytisinicline drug product for potential commercial launch. Achieve and Adare have begun a technology transfer following three development agreements that the two entities have signed with each other. We see multiple sources of cytisinicline manufacturing, especially one in the United States as a material positive for the company which provides flexibility and the ability to sidestep any future tariffs that may exist.

Milestones

- NDA Submission – 2Q:25
- Cytisinicline data published in journal Thorax – September 2025
- Erik Atkisson [appointed](#) as Chief Legal Officer – October 2025
- Completion of ORCA-OL trial – October 2025
- FDA data [submission](#) from patients with twelve months of exposure to cytisnicline – October 2025
- Award of CNPV for cytisnicline in a vaping indication – October 2025
- ICER [publishes evidence report](#) for cytisnicline – December 2025
- [Appointment](#) of Dr. Mark Rubinstein as Chief Medical Officer – January 2026
- Publication in Thorax journal: [Cytisinicline for Smoking Cessation](#) – February 2026
- Manufacturing partnership announced with Adare Pharma – March 2026
- Presentation at American Thoracic Society Conference – May 2026
- Phase III ORCA-V2 vaping trial initiation – 2026
- FDA target action date for cytisnicline NDA – June 20th, 2026
- Launch of cytisnicline – 1H:27

Valuation

We adjust our valuation to reflect additional shares expected to be issued and other claims on equity over the next 18 months. Furthermore, we move our estimated first sales to 2027 from 2026 and advance our NPV cash flow model ahead by one year. While Achieve management continues to point us to the June 20th, 2026 PDUFA date, we believe that the risks of a delay in approval have increased given the observations the FDA noted at Achieve's European manufacturer. With the 1H:27 target for product launch, a delay in approval is less likely to impact Achieve's expected timeline. The result of these changes generates a valuation of \$20 per share.

Summary

Achieve management confirmed the June 20th PDUFA date; however, issues at the company's manufacturers have raised the risk of a potential delay, especially if the questions cannot be resolved sufficiently prior to the anticipated approval date. The status and disposition of the observations is between the manufacturer and the FDA, which gives Achieve limited visibility on the process. In an effort to execute a stronger launch, management has pushed back its anticipated launch of cytisnicline to 1H:27 which will allow sufficient supply to be available and give more time to contract with payors. The marketing team continues its efforts with Omnicom to communicate with stakeholders and implement its digital campaign. We update our valuation to reflect a later start to commercialization and additional shares in the denominator over the next 18 months among other factors. To reflect these changes, we update our valuation to \$20 per share.

PROJECTED FINANCIALS

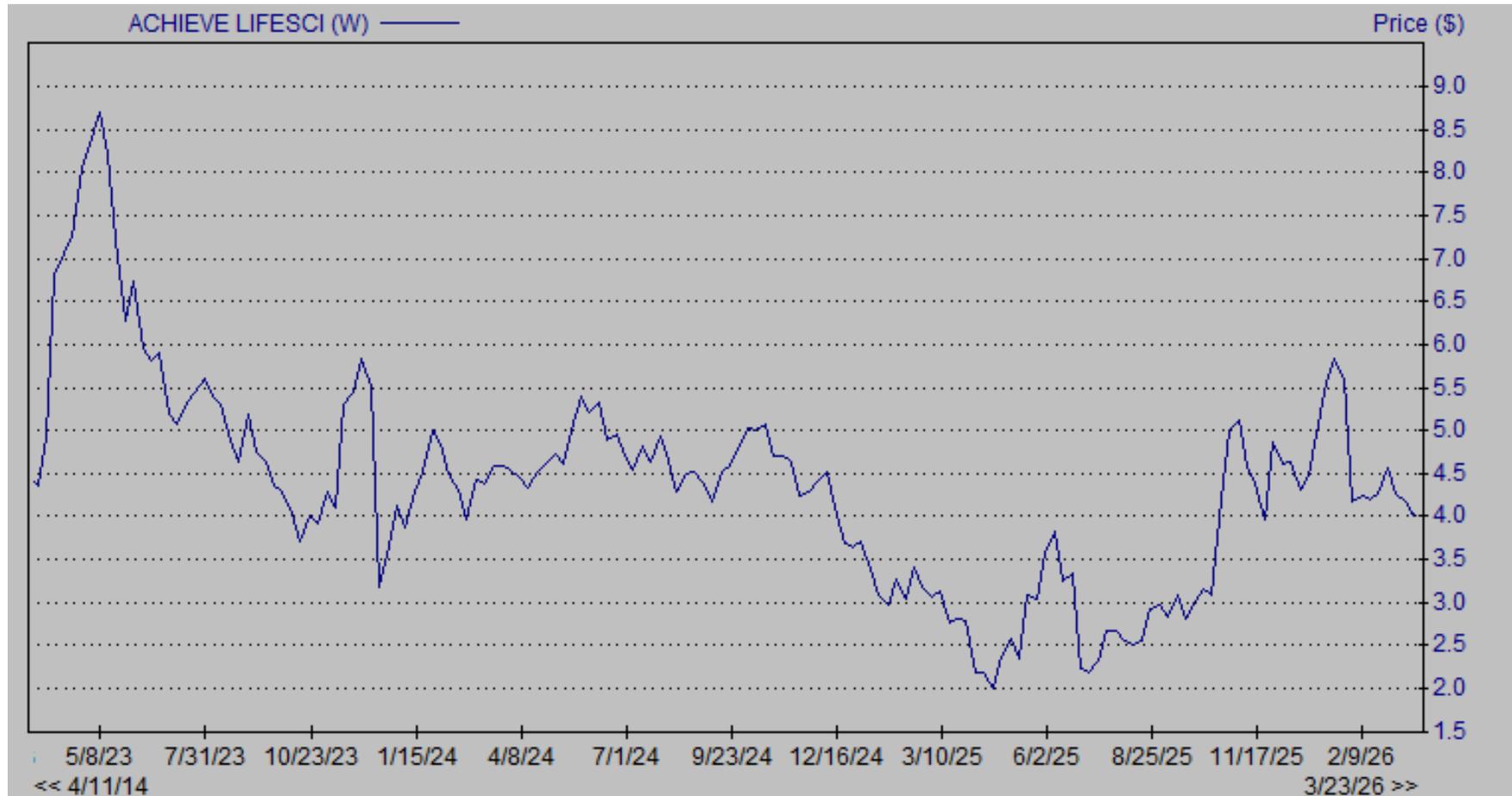
Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2024 A	Q1 A	Q2 A	Q3 A	Q4 A	2025 A	2026 E	2027 E
Total Revenues (\$MM)	\$0.0	\$20.7						
Growth	-					-	-	
R&D	\$22.8	\$7.1	\$6.7	\$5.3	\$3.9	\$23.0	\$29.0	\$0.0
G&A	\$16.3	\$5.8	\$5.9	\$9.4	\$10.9	\$31.9	\$29.0	\$29.6
S&M	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$26.1	\$31.5
Operating Income	(\$39.1)	(\$12.9)	(\$12.6)	(\$14.7)	(\$14.7)	(\$54.9)	(\$84.1)	(\$40.3)
<i>Operating Margin</i>								-194.7%
Interest Income	\$0.2	\$0.1	\$0.0	\$0.4	\$0.2	\$0.7	\$0.3	\$0.0
Total Other Income	(\$0.9)	(\$0.1)	(\$0.2)	(\$0.1)	(\$0.1)	(\$0.4)	\$0.0	\$0.0
Pre-Tax Income	(\$39.8)	(\$12.8)	(\$12.7)	(\$14.4)	(\$14.7)	(\$54.6)	(\$83.8)	(\$40.3)
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)	(\$14.4)	(\$14.7)	(\$54.7)	(\$83.8)	(\$40.3)
Reported EPS	(\$1.24)	(\$0.37)	(\$0.37)	(\$0.28)	(\$0.28)	(\$1.25)	(\$1.40)	(\$0.65)
<i>YOY Growth</i>						0%		
Shares Outstanding	32.1	34.7	34.7	51.0	53.3	43.6	59.7	62.0

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

HISTORICAL STOCK PRICE

Achieve Life Sciences, Inc. – Stock Price Chart¹



¹ Source: Zacks Research System

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