Zacks Small-Cap Research

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Achieve Life Sciences, Inc. (ACHV: NASDAQ)

ACHV: Looking Ahead to Resubmission

Our valuation approach employs a DCF model and a 15% discount rate. We apply an 85% probability of eventual cytisinicline 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 (8/17/2026)	$7.50
Valuation	**$21.00**

Achieve Life Sciences is developing cytisinicline for use as a smoking cessation treatment in the United States and rest of world. Pivotal studies have been completed with results demonstrating attractive safety & efficacy. Achieve received a complete response letter (CRL) in June 2026 for its NDA submission due to issues at its former manufacturer. It plans a resubmission in 4Q:26. While waiting for approval, the company is focused on pre-commercialization activities.

Existing cessation products provide limited effectiveness and produce unpleasant side effects including nausea, vivid dreams, insomnia & gastrointestinal 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 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 2027 commercialization of cytisinicline.

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.

OUTLOOK
SUMMARY DATA

52-Week High	**7.60**
52-Week Low	**2.55**
One-Year Return (%)	**194.1**
Beta	**2.2**
Average Daily Volume (sh)	**1,807,643**
Shares Outstanding (mil)	**102.9**
Market Capitalization ($mil)	**771.8**
Short Interest Ratio (days)	**10.7**
Institutional Ownership (%)	**82.0**
Insider Ownership (%)	**0.9**
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 2026 Estimate	**N/A**
P/E using 2027 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)
2025	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2026	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2027					$20.7 E
2028					$107.1 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2025	-$0.37 A	-$0.37 A	-$0.28 A	-$0.28 A	-$1.25 A
2026	-$0.19 A	-$0.80 A	-$0.21 E	-$0.26 E	-$1.51 E
2027					-$0.44 E
2028					$0.10 E

WHAT'S NEW

Achieve Life Sciences, Inc. (NASDAQ: ACHV) reported second quarter results, introducing a number of new faces and regulatory updates since the previous financial update in May. Achieve has added new individuals to both the executive ranks and the board. The company has enhanced its commercial leadership, Chemistry, Manufacturing and Controls (CMC), supply chain and quality functions on the management team. In the boardroom, new appointees bring extensive experience in commercialization, finance and medicine. After months of anticipation of its impending arrival, a Complete Response Letter (CRL) was returned to Achieve in June. As management consults with the FDA about the contents of the CRL, it is also preparing to resubmit the new drug application (NDA) for cytisinicline. Additionally, the company presented new safety data at the American Thoracic Society conference and was added to the Russell 2000 Index.

Financial and Operational Results

Achieve's 2Q:26 financial and operational results were detailed in a press release and Form 10-Q filing. No revenues were reported in 2Q:26. Operating expense was $18.4 million producing a net loss of $74.8 million or $0.80 per share. The substantial difference between operating expense and net loss is predominantly attributable to a change in warrant-related fair value to and issuance costs. For the quarter ending June 30th, 2026 versus the same prior year period:

- Research & development expense totaled $3.8 million, down 43% from $6.7 million, due to lower clinical trial costs and stock-based compensation. This was partially offset by higher manufacturing and supply chain costs related to the anticipated commercial launch. These costs included the purchase of raw cytisinicline inventory and the technology transfer to Adare;
- General & administrative expense was $14.6 million, up 149% from $5.9 million on higher employee expenses and commercial launch preparation;
- Net interest income was $1.2 million vs. $0 as interest from higher cash balances offset interest expense;
- Other expense of $57.6 million was related to change in fair value of warrant liability, change in fair value of pre-funded warrant liability and warrant issuance cost among other smaller miscellaneous items;
- Net loss was $74.8 million vs. $12.7 million or $0.80 and $0.37 per share, respectively.

As of June 30th, 2026, marketable securities, cash and equivalents totaled $187.3 million. This compares to a $36.4 million balance held at the end of 2025. At the end of the second quarter, Achieve carried convertible debt of $14.9 million on the balance sheet. Cash used in operations during the first six months of 2026 was $17.9 million versus $20.2 million in the same prior year period. Cash from financing was $168.5 million which includes gross proceeds from the $180 million financing that was funded by a consortium of healthcare investors. It included warrants that could raise another $174 million upon FDA approval of cytisinicline.

New Executive and Board Members Added

CEO Andrew Goldberg, MD, assumed the top spot at Achieve in mid-April and was added to the company's board of directors. Two other directors joined the board at that time along with Dr. Goldberg, including Lucian Iancovici, MD, a managing director at TPG and Aaron Royston, MD, a managing partner at venBio. Announced alongside first quarter results, Dr. Iancovici was elevated to the role of Chairman of the Board and Christopher Martin was added to the board. Early June brought two new board members: Jeffrey Farrow and Reid Waldman, MD. Mr. Farrow brings experience as CFO and has supported three commercial launches of products at Hyperion, Global Blood Therapeutics and Tarsus. Dr. Waldman is a dermatologist and the founder and CEO of Veradermics, a firm that is developing therapies for hair loss.

Other members were added to the executive team to strengthen the commercialization effort. Mark Zappia joined as Senior Vice President, Commercial and Jim Willis joined as Vice President of Sales and Sales Enablement where he will lead the field force. These individuals were part of the team at Verona Pharma where they led the commercial operations for the launch of Ohtuvayre, a therapy for chronic obstructive pulmonary disease (COPD) which has generated almost $550 million in revenues over the trailing four quarters and is expected to generate over $800 million in 2026.[1] In early August, Achieve announced the addition of two more executives who will lead CMC, supply chain and quality functions at the company. Ronald Dadino was appointed as SVP, CMC and Supply Chain at

[1] Estimates sourced from Evaluate, Ltd.

Achieve where he will be responsible for manufacturing, technical operations, and the end-to-end cytisinicline supply chain, from raw material through finished, packaged product. He has more than 40 years of experience in pharmaceutical chemistry, manufacturing and controls, technical operations, and supply chain. He began his career at Merck and later moved to Johnson & Johnson where he was responsible for developing and commercializing first in class products. He has also held positions at Aclaris Therapeutics, Orchestra Biomed, Palladio Biosciences and Sling Therapeutics. Gloria Cosgrove was appointed as SVP, Quality where she will lead Achieve's quality organization across manufacturing, clinical, and regulatory quality. Ms. Cosgrove began her career at Boehringer Ingelheim in Global Quality Assurance where she spent 26 years. She later was a senior director at Regeneron Pharmaceuticals and Synageva BioPharma. Most recently she was a VP and SVP at Seres Therapeutics and Lyra Therapeutics where she held leadership roles in Quality.

Sopharma Dispute

In 2017, Achieve Life Sciences entered into an exclusive, long-term agreement with Sopharma to develop and commercialize the smoking cessation treatment cytisinicline. The agreement licensed territories outside of Sopharma's core region in Central and Eastern Europe to Achieve. The original agreement called for Sopharma to supply cytisinicline active pharmaceutical ingredients (API) to Achieve for sale in licensed markets for a per unit fee. The arrangement also provided Sopharma with a mid-single-digit royalty on net sales. In 2023, Achieve and Sopharma conducted mock inspections and engaged consultants in preparation for a regulatory review. However, as Achieve prepared to submit its NDA, it felt that Sopharma would not be able to pass an FDA inspection if several concerns were not addressed. It is unclear what, if any, arrangements came from this disagreement, but Achieve began to use third party manufacturers including Adare to manufacture cytisinicline.

Sopharma alleged that Achieve's use of third-party manufacturers is a breach of the agreement. In July 2026, Sopharma filed an arbitration demand alleging breach of the Sopharma Supply Agreement. Sopharma is seeking actual, compensatory, incidental and consequential damages; costs and attorneys' fees; restitution; declaratory relief; and an order requiring Achieve to include Sopharma as the designated manufacturer in any future NDA submission. Achieve disputes these claims; however, it is unclear what impact this may have on Achieve's timeline for cytisinicline development and legal liability. At this point, we believe that our discount rate and probability of success capture events such as these until such time as they can be quantified more accurately.

Data Presentation at the American Thoracic Society Meeting

Principal investigator Nancy Rigotti, MD, presented Ongoing Research of Cytisinicline for Addiction Open Label (ORCA OL) data at the American Thoracic Society (ATS) 2026 Annual Meeting. The event was held in Orlando, Florida from May 15th to 20th, 2026. Details of the event were included in a May 19th press release.

The presentation includes the final clinical dataset supporting Achieve's new drug application (NDA). The enrolled population included smokers (84.6%), e-cigarette users (12.8%), and dual users (2.5%). 66.3% of the participants experienced one or more treatment-emergent adverse events, the majority of which were considered unrelated or unlikely to be related to cytisinicline. Almost 95% of these events were mild or moderate with serious adverse events in 6.5% of participants. Common adverse events include abnormal dreams, insomnia and upper respiratory tract infection. 5.7% of participants discontinued the trial due to treatment-related adverse events.

The presentation's title was *Scientific Tobacco Action Committee Scientific Symposium — "For the First Time in Forever": Cytisinicline, a New Medication for Nicotine Dependence*. It was held on the morning of May 20th. Along with Dr. Rigotti, Mark Rubinstein, MD, Achieve's Chief Medical Officer, presented comparative effectiveness data in a poster session entitled Comparative Effectiveness of Cytisinicline and Varenicline for Smoking Cessation: A Matching-Adjusted Indirect Comparison (MAIC). It was also held on May 20th.

April 2026 Private Placement

Along with the announcement of Dr. Goldberg taking the CEO role, Achieve also executed a substantial capital raise. The deal provides $180 million of financing upfront and another $174 million potentially available from warrants that will expire 20 days after FDA approval of cytisinicline. Assuming approval and warrant exercise, this structure will generate additional capital to expand sales efforts as first commercialization activities begin. The private placement issued 49,418,069 shares of common stock at $3.635 per share and 100,500 pre-funded warrants at $3.634 per pre-funded warrant. The transaction generated gross proceeds of $180 million.

One common warrant was attached to each share of common stock and prefunded warrant, bringing the total to 49,518,569 warrants. They may be exercised at $3.51 per share at any time after issuance and carry the aforementioned expiration 20 business days after FDA approval of cytisinicline for smoking cessation. If cytisinicline is not approved, they expire after two years.

Proceeds from the raise will be used to fund a Phase III trial for cytisinicline for e-cigarette cessation, the commercialization of cytisinicline and for working capital and general corporate purposes.

Investors who participated in the deal include Frazier Life Sciences, TPG Life Sciences Innovations, venBio Partners, Paradigm BioCapital Advisors and Marshall Wace. The deal also included participation from both new and existing investors, including Coastlands Capital, Dialectic Capital, Janus Henderson Investors, LifeSci Venture Partners, Logos Capital, Propel Bio Partners, Spruce Street Capital, Venrock Healthcare Capital Partners, Vivo Capital and Wellington Management. Morgan Stanley served as the sole placement agent for the transaction.

NDA Submission and Acceptance Timeline

Achieve announced its NDA submission of cytisinicline for smoking cessation in a June 26th, 2025 press release. On September 3rd, 2025, the company reported FDA acceptance of its NDA and the assignment of a June 20th, 2026 Prescription Drug User Fee Act (PDUFA) date. Achieve engaged a European manufacturer for cytisinicline which later received two observations during an FDA inspection related to solid oral dose manufacturing. This was reported in Achieve's 2025 Form 10-K filed in March. A follow-up press release on April 15th, 2026 reported that the FDA issued an OAI[2] classification from the inspection. As a result, Achieve indicated that it expected to receive a CRL from the FDA. On June 22nd, Achieve announced that the FDA had delivered a CRL which cited manufacturing-related observations arising from a current Good Manufacturing Practice (cGMP) inspection of the facility. The agency also cited incomplete final product labeling as a reason for the letter. The deficiencies cited relate to Achieve's former European manufacturer and are not expected to impact the new domestic partner, which is expected to produce cytisinicline from this point forward.

Achieve intends to resubmit the New Drug Application (NDA) listing Adare as manufacturer in 4Q:26. This timeline supports potential FDA approval by 1H:27, which is expected to be followed by commercial launch.

Milestones

- FDA awards Commissioner's National Priority Voucher (CNPV) for vaping indication – October 2025
- Appointment of Dr. Mark Rubinstein as Chief Medical Officer – January 2026
- Publication in Thorax journal: Cytisinicline for Smoking Cessation – February 2026
- Presentation at Society for Research on Nicotine & Tobacco (SRNT) meeting – March 2026
- Manufacturing partnership announced with Adare Pharma – March 2026
- Publication in Nicotine & Tobacco Research – March 2026
- Technology transfer to Adare – April 2026
- Appointment of Andrew Goldberg as CEO – April 2026
- Private placement – April 2026
- Appointment of new board member and commercialization executives – May 2026
- Presentation at the American Thoracic Society Conference – May 2026
- Achieve added to Russell 2000 index – June 2026
- FDA issues CRL for cytisinicline – June 2026
- Phase III ORCA-V2 vaping trial initiation – 2026
- Resubmission of cytisinicline NDA for smoking cessation – 4Q:26
- FDA approval of cytisinicline for smoking cessation – 1H:27
- Launch of cytisinicline – 2027

[2] Official Action Indicated (OAI)

Summary

During the second quarter Achieve shifted its manufacturing to Adare and made substantial changes to the leaders running the company. New CEO Andrew Goldberg brought onboard a new slate of directors and senior executive leaders to advance cytisinicline across the finish line. One of his first actions was the execution of a capital raise led by several distinguished health care investors which added $180 million to the company's coffers. The structure of the deal provides additional capital through warrants that must be exercised following FDA approval of cytisinicline.

Achieve did not hold a call in conjunction with the second quarter report and in coming periods will conduct conference calls with investors around significant regulatory and commercial milestones. We expect stakeholders to have an opportunity to publicly interact with management upon the resubmission of cytisinicline to the FDA and at investor meetings and industry conferences.

PROJECTED FINANCIALS

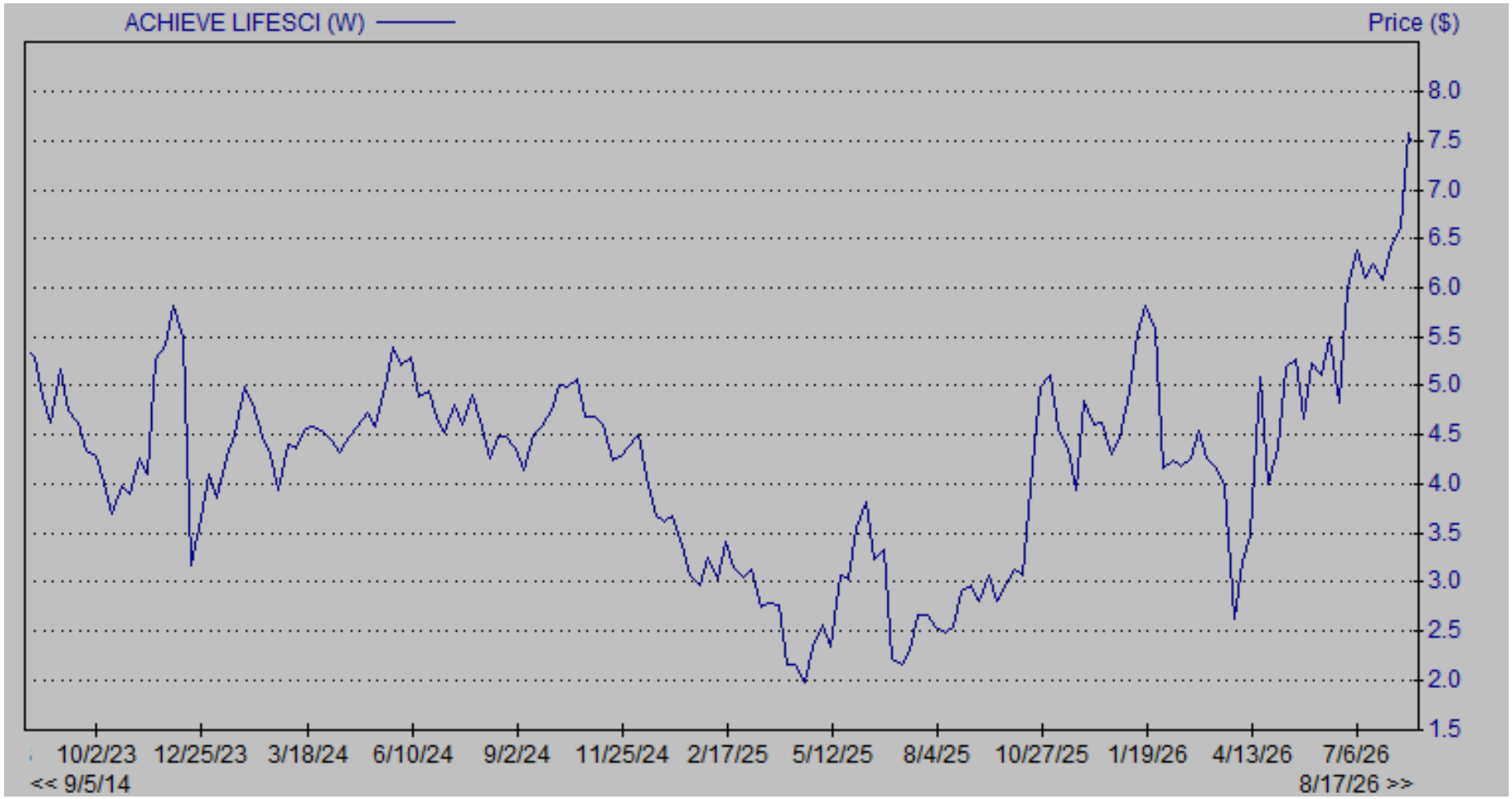
Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2025 A	Q1 A	Q2 A	Q3 E	Q4 E	2026 E	2027 E	2028 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$20.7**	**$107.1**
Growth	-							517%
R&D	$23.0	$3.3	$3.8	$8.0	$9.0	$24.1	$20.0	$15.0
G&A	$31.9	$7.2	$14.6	$14.2	$18.0	$54.0	$29.6	$30.2
S&M	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$31.5	$42.0
Operating Income	($54.9)	($10.5)	($18.4)	($22.2)	($27.0)	($78.1)	($60.3)	$19.9
Interest Income	$0.7	$0.0	$1.2	$0.1	$0.1	$1.4	$0.8	$0.2
Total Other Income	($0.4)	$0.3	($57.6)	$0.0	$0.0	($57.3)	$0.0	$0.0
Pre-Tax Income	($54.6)	($10.2)	($74.8)	($22.1)	($26.9)	($133.9)	($59.5)	$20.1
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	($54.7)	($10.2)	($74.8)	($22.1)	($26.9)	($133.9)	($59.5)	$20.1
	0%							
Reported EPS	**($1.25)**	**($0.19)**	**($0.80)**	**($0.21)**	**($0.26)**	**($1.51)**	**($0.44)**	**$0.10**
Shares Outstanding	43.6	53.4	93.5	103.1	104.5	88.6	136.9	200.0

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

HISTORICAL STOCK PRICE

Achieve Life Sciences, Inc. – Stock Price Chart[3]



[3] Source: Zacks Research System

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