Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

November 10, 2025
John D. Vandermosten
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
101 N. Wacker Drive, Chicago, IL 60606

Achieve Life Sciences, Inc. (ACHV: NASDAQ)

ACHV: FDA's CNPV Awarded for Vaping

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 (11/7/2025)	$4.59
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. Pivotal studies have been completed with safety & efficacy results exceeding expectations. Achieve is now awaiting its target action date of June 20th 2026 and 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. 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.

A pivotal vaping trial is planned for 2H:26. 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	**5.78**
52-Week Low	**1.84**
One-Year Return (%)	**-8.2**
Beta	**1.7**
Average Daily Volume (sh)	**1,523,946**
Shares Outstanding (mil)	**53.2**
Market Capitalization ($mil)	**244.2**
Short Interest Ratio (days)	**6.7**
Institutional Ownership (%)	**59.5**
Insider Ownership (%)	**4.3**
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 A	$0.0 A	$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 A	-$0.28 A	-$0.22 E	-$1.19 E
2026					-$1.07 E
2027					$0.69 E

© Copyright 2025, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Achieve Life Sciences, Inc. (NASDAQ: ACHV) reported third quarter results, wrapping up an intense three months since its prior quarterly release. Since August, Achieve has communicated the acceptance of its new drug application (NDA), the assignment of a target action date for cytisinicline, the addition of new executives, publication in the journal Thorax, the award of the Commissioner's National Priority Voucher (CNPV) and the submission of its 120-day safety update. The company has also made substantial progress developing its commercialization strategy which is thoroughly discussed in a series of video interviews with CEO Rick Stewart and Chief Commercial Officer (CCO) Jaime Xinos. Company accomplishments have also been shared at multiple fall investor conferences.

Financial and Operational Results

Achieve's third quarter 2025 financial and operational results were detailed in a press release, Form 10-Q filing and a webcast which provided analysts the opportunity to ask questions. No revenues were reported in 3Q:25. Operating expense was $14.7 million producing a net loss of ($14.4) million or ($0.28) per share. For the quarter ending September 30th, 2025 and versus the same comparable prior year quarter:

- Research & development expense totaled $5.3 million, a 30% drop from $7.6 million, due to the trial expenses for ORCA-OL safety trial recognized in the prior year period;
- General & administrative expense was $9.4 million, up 93% from $4.9 million on higher employee expenses and commercial launch preparation;
- Net other income was $251,000 vs. ($46,000) as interest income offset interest expense and other minor miscellaneous items;
- Net loss was ($14.4) million vs. ($12.5) million or ($0.28) and ($0.36) per share, respectively.

As of September 30th, 2025, cash and equivalents totaled $48.1 million. This compares to a $34.4 million balance held at the end of 2024. At quarter end, Achieve carried convertible debt of $9.9 million on the balance sheet which includes accrued interest. In October 2025, the company drew down an additional $5.0 million upon achieving its milestone of NDA acceptance. Cash used in operations during 3Q:25 was ($11.3) million versus ($10.4) million in the same prior year period. Following the end of the reporting period, in October 2025, 421,500 warrants were exercised at $3.00 generating proceeds of $1.3 million.

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.

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 cytisinicline 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 cytisinicline. When examining the COPD subset, the relative benefit of cytisinicline was greater in the COPD arm than it was for the non-COPD arm at six weeks of cytisinicline 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

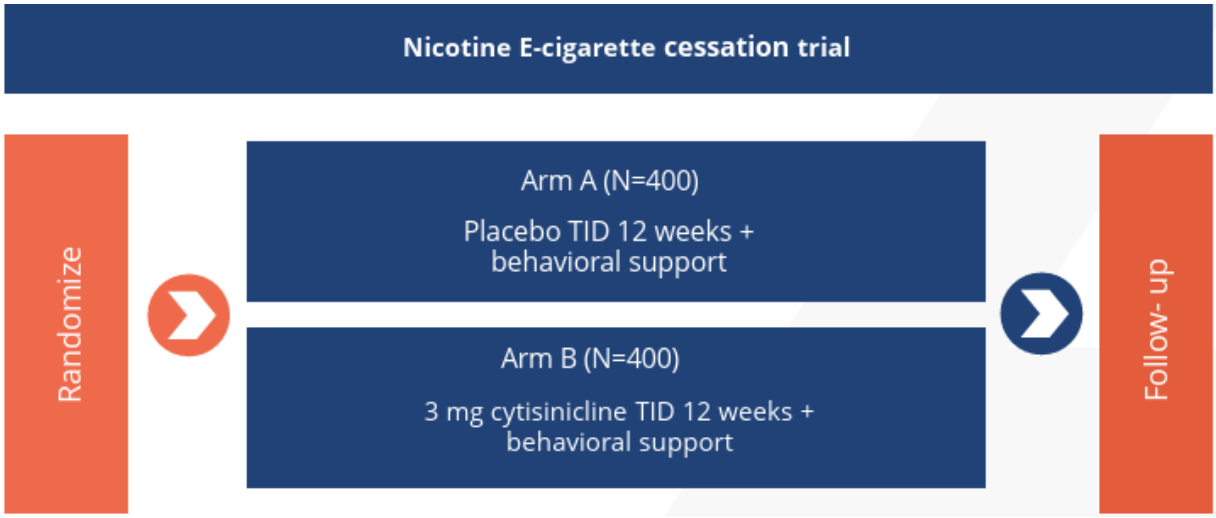
at 5.3 vs. 5.2. See the link for a graphic representation. The authors concluded that "Cytisinicline's low side effect profile and high treatment adherence make it an appealing option for those struggling to quit smoking, potentially lowering medical costs and improving long-term health outcomes."

National Priority Voucher

Achieve was awarded one of nine National Priority Vouchers for cytisinicline 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.

Exhibit I – Phase III ORCA-V2 Vaping Trial Qualifies for CNPV



Source: Achieve Life Sciences November 2025 Investor Presentation

Appointments and Promotions

Achieve announced the appointment of Dr. Mark Rubinstein as interim Chief Medical Officer (CMO), the promotion of Craig Donnelly to Chief Operations Officer (COO) and the addition of Erik Atkisson as Chief Legal Officer (CLO). Dr. Rubinstein, M.D. succeeds Cindy Jacobs, Ph.D., M.D. in the role. Dr. Rubinstein was hired as Head of Medical Affairs at Achieve in October 2024 having previously served as Head of Medical Affairs at Blip, a smoking cessation company. Dr. Jacobs is expected to provide advisory services as the new CMO ramps up in the role. Craig Donnelly joined Achieve in 2022 as Executive Vice President of Chemistry, Manufacturing and Controls (CMC). As COO, Craig will lead the integration of Achieve's supply chain and manufacturing activities with its commercial strategy. In late October, Achieve added a Chief Legal Officer to its ranks with the appointment of Erik Atkisson. Erik was previously at Rain Oncology and had over 25 years of experience in the pharmaceutical and biotechnology industries. He will oversee Achieve's legal strategy, corporate governance, compliance and risk management.

Video Series Interviews

CEO Rick Stewart and CCO Jaime Xinos participated in a series of video interviews covering a range of topics including Omnicom's role in the commercialization effort, to Artificial Intelligence (AI) and Achieve's work in vaping cessation. The two executives enumerated near term milestones, shared anecdotal patient successes and reviewed Achieve's balance sheet. See below for links to the excerpts.

Exhibit II – Achieve Executive Interviews



Source: Video Interview Screen Capture

- Achieve Near Term Milestones
- Three Imperatives
- Commercialization Approach
- Artificial Intelligence
- Anecdotal Successes
- Achieve Balance Sheet
- Parallels Between GLP-1 Agonists and Cytisinicline
- Achieve's Efforts in Vaping Cessation
- Omnicom's Role With Achieve

Sopharma Relationship

Achieve noted in its 10-Q filing that it harbors concerns 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 now 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 in its latest slide deck 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.

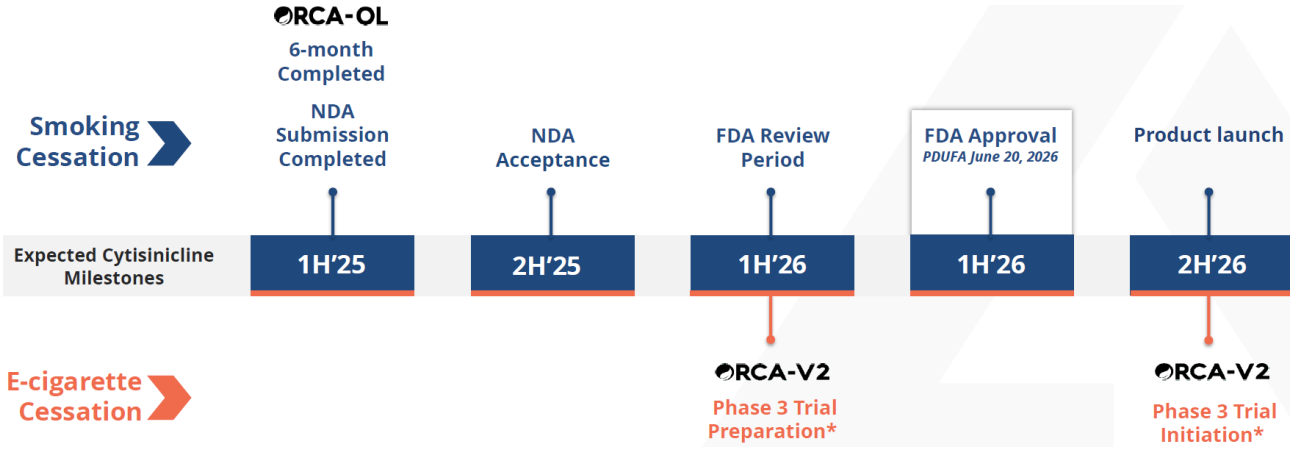
It is too early to tell how the dispute with Sopharma will resolve; however, we note that Achieve will owe Sopharma a royalty of 6% of sales. While moving beyond Sopharma provides more flexibility to source the product, it also lowers the barriers of entry for others when cytisinicline's IP expires.

Milestones

In an early November press release, Achieve announced that it had submitted its 120-day safety update to the FDA related to its new drug application. This completes all of the anticipated submissions for the FDA to complete its review of cytisinicline and remain on track for the target action date in June 2026. Data was generated from the ORCA-OL safety trial which was a remarkable success. In the trial, 334 individuals completed one year of treatment which exceeds the 100 patients that the FDA requested. Adverse events were mostly mild and no serious events were deemed to be treatment related. The high rate of enrollment and compliance is a vote of confidence in cytisinicline which suggests cytisinicline will be well received by providers, payors and patients if approved.

- Development of cytisinicline product label for smoking cessation – 1H:25
- Completion of six months of ORCA-OL safety data for 300 subjects – January 2025
- Selection of 3rd party logistics partner – 2Q:25
- NDA Submission – 2Q:25
- BTIG Virtual Biotechnology Conference attendance – July 2025
- Attendance at HC Wainwright conference – September 2025
- Attendance at Lake Street Conference – September 2025
- Cytisinicline data published in journal Thorax – September 2025
- New hire inducement awards granted – October 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 cytisinicline – October 2025
- Phase III vaping trial initiation – 2H:26
- FDA target action date for cytisinicline NDA – June 20th, 2026
- Launch of cytisinicline – Late 2026

Exhibit III – Achieve Development Timeline



Source: Achieve Life Sciences November 2025 Investor Presentation

Summary

Achieve has experienced substantial activity since the second quarter report. Its NDA has been accepted, a PDUFA date has been assigned, it has submitted its one-year safety data and has received a CNPV to help accelerate its vaping program. Management has held various communications with investors and continues to refine its commercialization strategy. Achieve also strengthens its executive ranks with new promotions and additions that prepare it to be a commercial entity. We maintain our valuation of $25 per share.

PROJECTED FINANCIALS

Achieve Life Sciences, Inc. - Income Statement

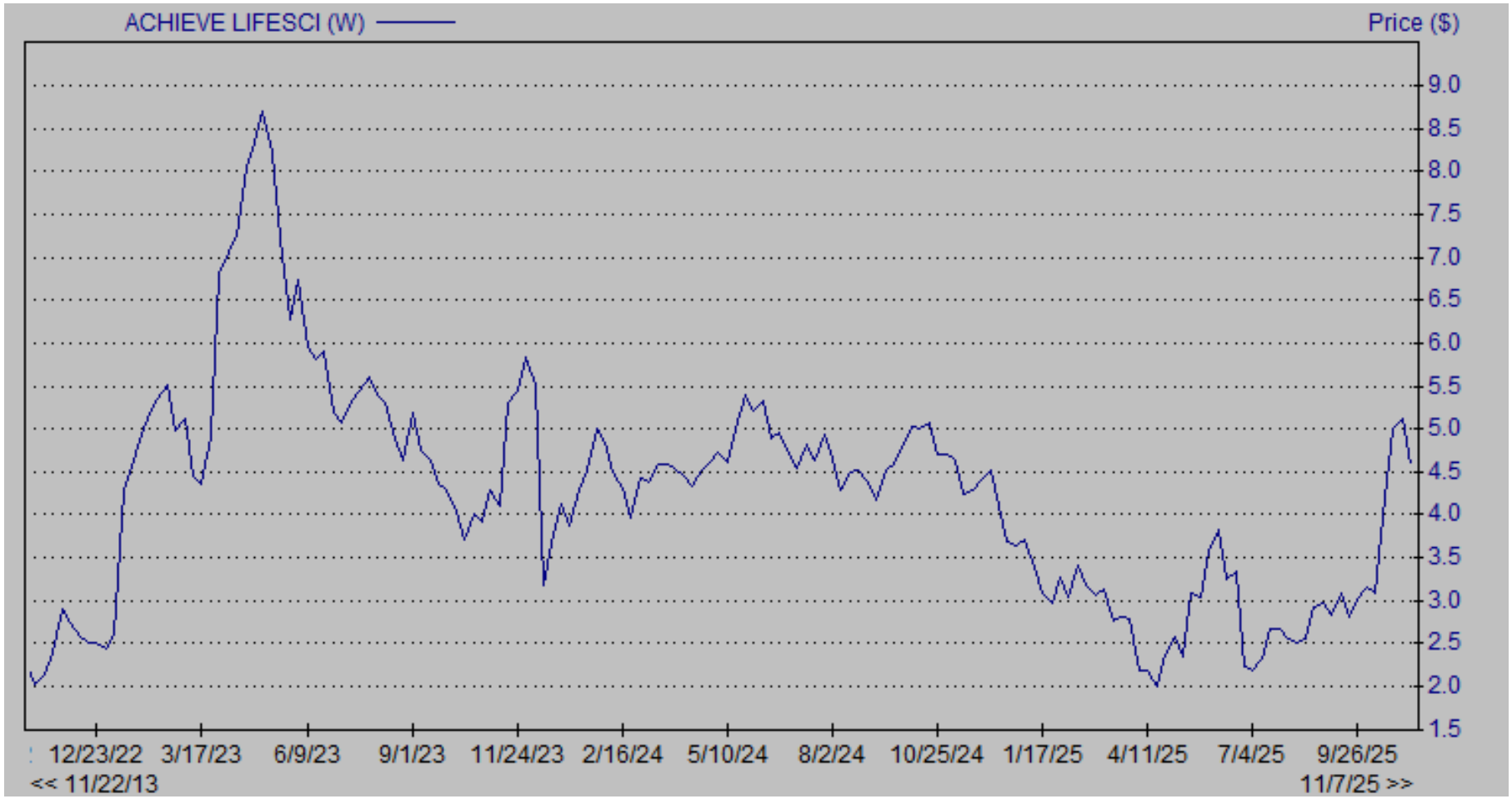
Achieve Life Sciences, Inc.	2024 A	Q1 A	Q2 A	Q3 A	Q4 E	2025 E	2026 E	2027 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$20.1**	**$103.6**
Growth	-					-	-	417%
R&D	$22.8	$7.1	$6.7	$5.3	$1.8	$20.9	$29.0	$0.0
G&A	$16.3	$5.8	$5.9	$9.4	$6.6	$27.6	$29.0	$29.6
S&M	$0.0	$0.0	$0.0	$0.0	$5.0	$5.0	$26.1	$31.5
Operating Income	($39.1)	($12.9)	($12.6)	($14.7)	($13.4)	($53.5)	($64.1)	$42.6
Operating Margin							*-319.4%*	*41.1%*
Interest Income	$0.2	$0.3	$0.2	$0.6	$0.7	$0.0	$0.0	$0.0
Total Other Income	($0.9)	($0.3)	($0.3)	($0.3)	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($39.8)	($12.8)	($12.7)	($14.4)	($12.7)	($53.5)	($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)	($12.7)	($14.4)	($12.7)	($53.6)	($64.1)	$42.6
Reported EPS	**($1.24)**	**($0.37)**	**($0.37)**	**($0.28)**	**($0.24)**	**($1.23)**	**($1.07)**	**$0.69**
YOY Growth								
Shares Outstanding	32.1	34.7	34.7	51.0	53.3	43.4	59.7	62.0

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

© Copyright 2025, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE

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



[1] Source: Zacks Research System

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, John Vandermosten, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

© Copyright 2025, Zacks Investment Research. All Rights Reserved.