Zacks Small-Cap Research

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Achieve Life Sciences, Inc. (ACHV: NASDAQ)

ACHV: Achieve's Busy Day

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 (7/2/2025)	$2.26
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.

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 (%)	**-50.8**
Beta	**1.6**
Average Daily Volume (sh)	**543,185**
Shares Outstanding (mil)	**49.8**
Market Capitalization ($mil)	**112.5**
Short Interest Ratio (days)	**9.0**
Institutional Ownership (%)	**41.6**
Insider Ownership (%)	**9.7**
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 (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 E	$0.0 E	$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	-$0.36 E	-$0.25 E	-$0.22 E	-$1.16 E
2026					-$1.07 E
2027					$0.69 E

WHAT'S NEW

Achieve Life Sciences, Inc. (NASDAQ: ACHV) posted a flurry of press releases last week announcing the submission of its new drug application (NDA), a partnership with Omnicom for cytisinicline commercialization, a proposed public offering and the pricing of the offering. The capital raise was closed on June 30th. This is the culmination of more than a decade of work developing cytisinicline for smoking cessation.

Now that the development phase of cytisinicline for smoking cessation is coming to a close, we look towards the regulatory and commercialization phases. We expect to see the FDA formally accept the NDA by late August and Achieve's management team to turn its attention towards the sales effort. Assuming normal turnaround times, we expect the FDA to set a target action date sometime in 2Q:26.

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. We expect to see acceptance of the NDA within 60 days and further expect additional safety data from the ongoing ORCA-OL trial to be shared with the agency near year end.

Commercialization Partnership

Now that the new drug application has been submitted, Achieve is further 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.

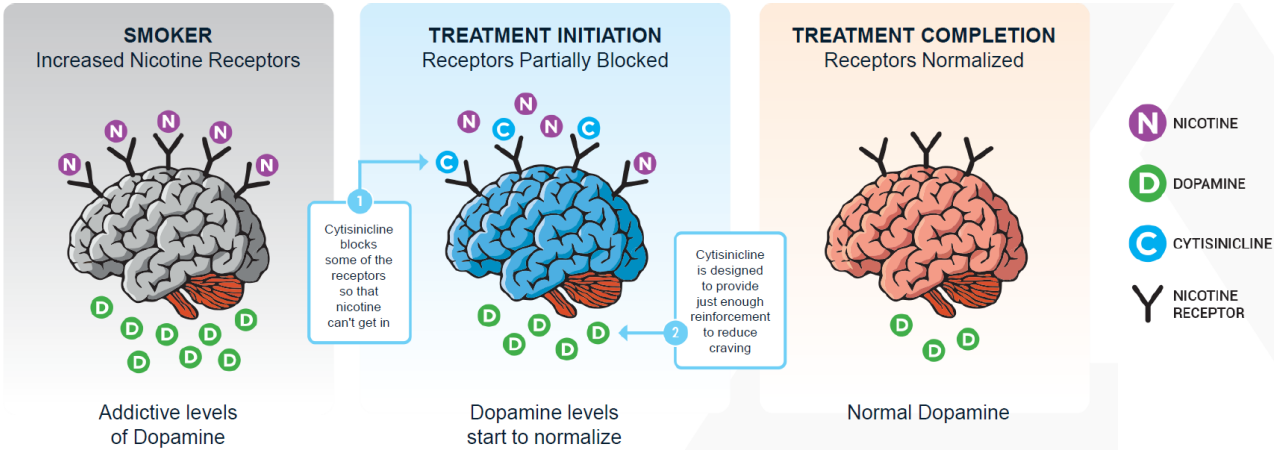
Public Offering

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.

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 I – Cytisinicline's Dual-Acting Mechanism of Action



Source: Achieve Life Sciences March 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 May 2025, a third DSMC safety review was completed which also found no unexpected treatment-related adverse events. As of the first quarter reporting date, more than 100 subjects had completed one year of cytisinicline treatment. Furthermore, about 75% of the 479 (~360) individuals remained on treatment in the trial. We think that it is a material real-world positive that so many participants would remain on a smoking cessation product for that long a period suggesting that cytisinicline is well tolerated. 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]

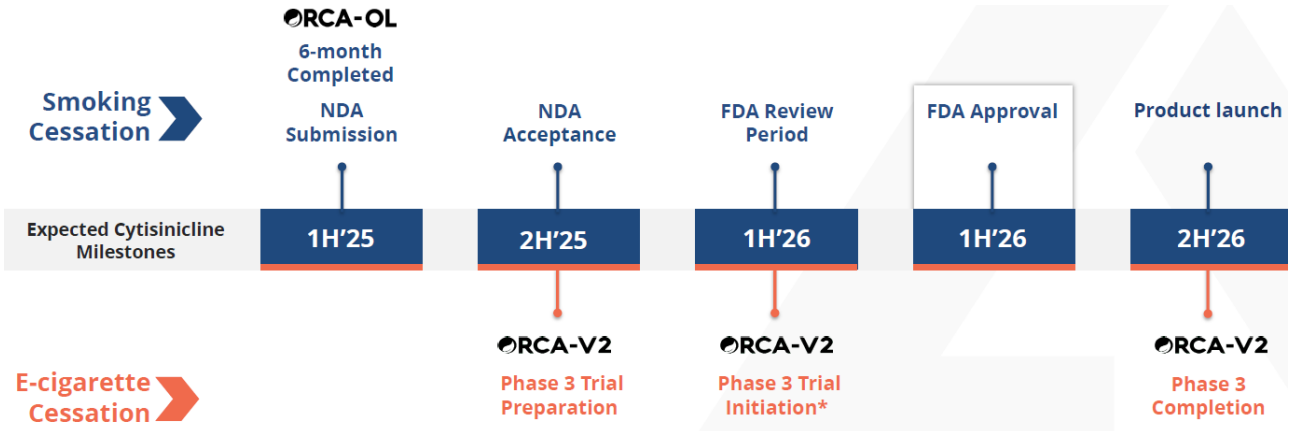
Achieve expects to complete the one-year safety data package in the next few months and will submit this to the FDA by the 120-day safety review milestone. This should be around year-end 2025. Achieve expects that it will far exceed the 100-patient minimum required for one year of safety observations 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
- 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 – 3Q:26

Exhibit II – Achieve Development Timeline



Source: Achieve March 2025 Corporate Presentation

Valuation

We make several adjustments to our valuation model, adding additional shares to the balance sheet related to the June 2025 transaction, moving forward our discounted cash flow (DCF) model ahead by one year and we increase our probability of success following the submission of the new drug application. We think there is a high probability of NDA acceptance and will increase our probability of success further when the package is accepted by the FDA.

Summary

Achieve has submitted its NDA and takes further steps in its commercialization preparations. The company also raises additional capital on the back of the FDA submission and increases its treasure chest by approximately $41 million. 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

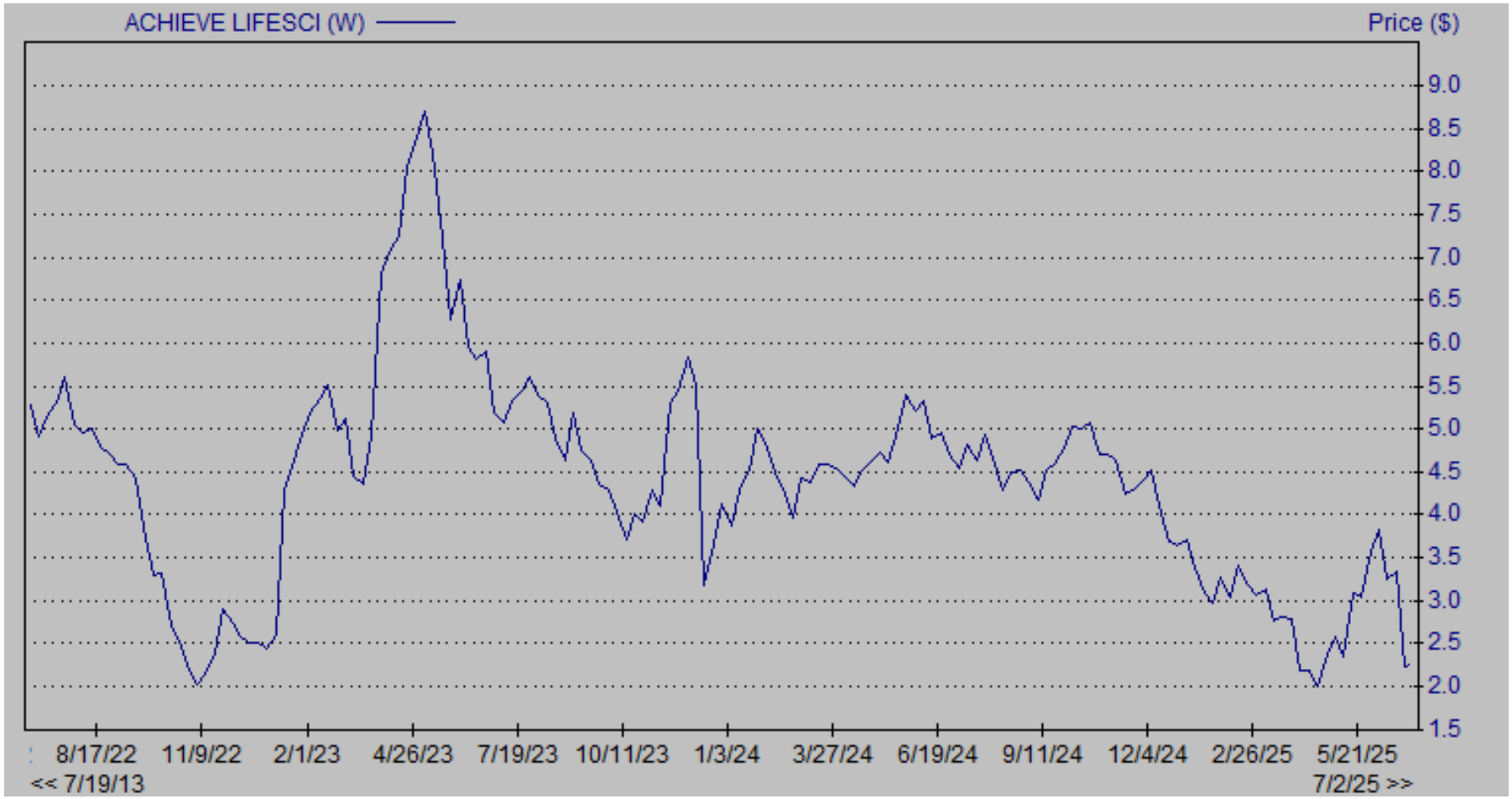
Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2024 A	Q1 A	Q2 E	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	$5.4	$3.5	$1.8	$17.8	$29.0	$0.0
G&A	$16.3	$5.8	$6.2	$7.4	$8.6	$28.0	$29.0	$29.6
S&M	$0.0	$0.0	$1.1	$2.0	$3.0	$6.1	$26.1	$31.5
Operating Income	($39.1)	($12.9)	($12.7)	($12.9)	($13.4)	($51.9)	($64.1)	$42.6
Operating Margin							*-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)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($39.8)	($12.8)	($12.5)	($12.8)	($12.7)	($51.9)	($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)	($12.5)	($12.8)	($12.7)	($51.9)	($64.1)	$42.6
Reported EPS	**($1.24)**	**($0.37)**	**($0.36)**	**($0.25)**	**($0.22)**	**($1.16)**	**($1.07)**	**$0.69**
YOY Growth								
Shares Outstanding	32.1	34.7	35.1	51.0	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 Chart[2]



[2] Source: Zacks Research System

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