

## Achieve Life Sciences, Inc.

(ACHV: NASDAQ)

### ACHV: Preparations Continue as PDUFA Date Assigned

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 (9/19/2025)

\$2.82

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 20<sup>th</sup> 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 & 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 (%)	-38.2
Beta	1.5
Average Daily Volume (sh)	1,387,433

Shares Outstanding (mil)	51.1
Market Capitalization (\$mil)	134.9
Short Interest Ratio (days)	4.6
Institutional Ownership (%)	61.4
Insider Ownership (%)	3.9

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 2025 Estimate	N/A
P/E using 2026 Estimate	N/A

Zacks Rank	N/A
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Risk Level

Type of Stock

Industry

Above Average

Small-Growth

Med-Drugs

## ZACKS ESTIMATES

### Revenue

(In millions of US\$)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(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 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) announced that its new drug application (NDA) for cytisinicline has been accepted by the FDA in a September 3<sup>rd</sup> press release. Other important developments include the appointment of two internal employees to interim Chief Medical Officer (CMO) and Chief Operations Officer (COO). The promotions reflect a broader change to the executive ranks as the company prepares to transition from a development company to a commercial organization. Achieve has also participated in two September conferences in New York, providing the opportunity for investors to receive an update on the company's progress and conduct 1:1 meetings.

### **NDA Submission and Acceptance**

Achieve announced its NDA submission of cytisinicline for smoking cessation in a June 26<sup>th</sup> [press release](#). On September 3<sup>rd</sup>, the company reported FDA acceptance of its NDA and the assignment of a June 20<sup>th</sup>, 2025 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. The other outstanding regulatory milestone is the submission of the one-year ORCA-OL safety data which is expected to be shared with the agency in October.

### **Appointments and Promotions**

Achieve announced the [appointment](#) of Dr. Mark Rubinstein as interim Chief Medical Officer (CMO) and the [promotion](#) of Craig Donnelly to Chief Operations Officer (COO). 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.

### **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.

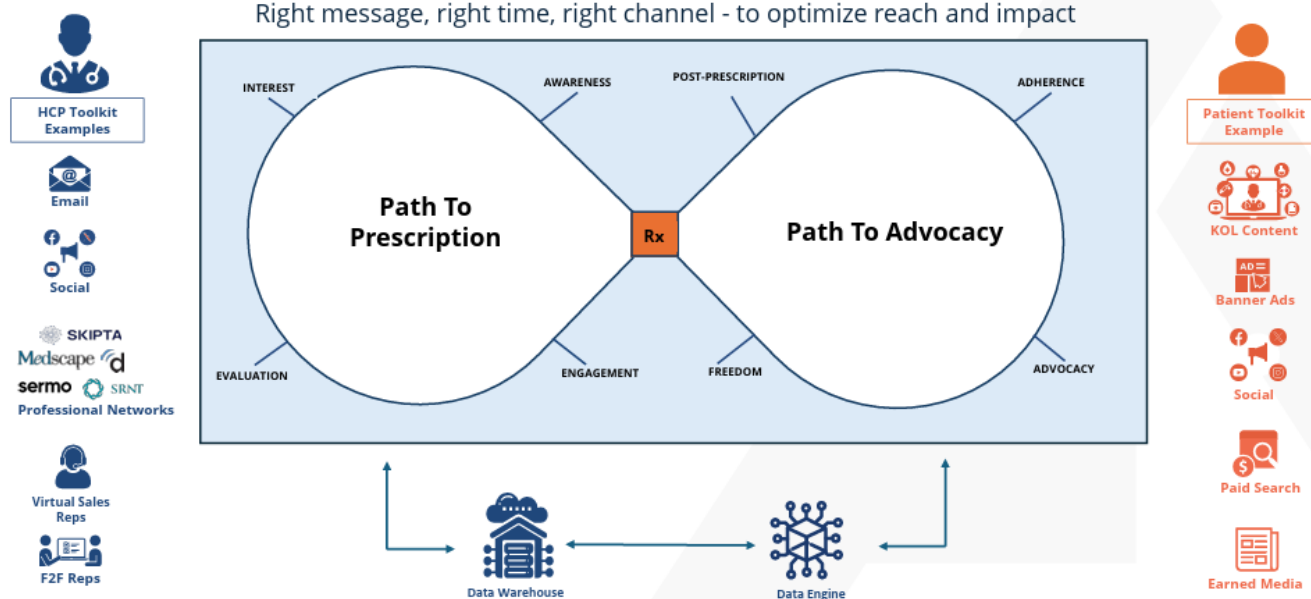
Achieve will work with Omnicom subsidiary Credera, which is focused on digital transformation services. Credera combines consulting, artificial intelligence (AI) and technology expertise to build consumer technology platforms, integrate marketing technology systems and provide strategic consulting services. It will help Achieve 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.

## Exhibit I – Launch Focus on Omnichannel Approach

Right message, right time, right channel - to optimize reach and impact



Source: Achieve Life Sciences August 2025 Investor Presentation

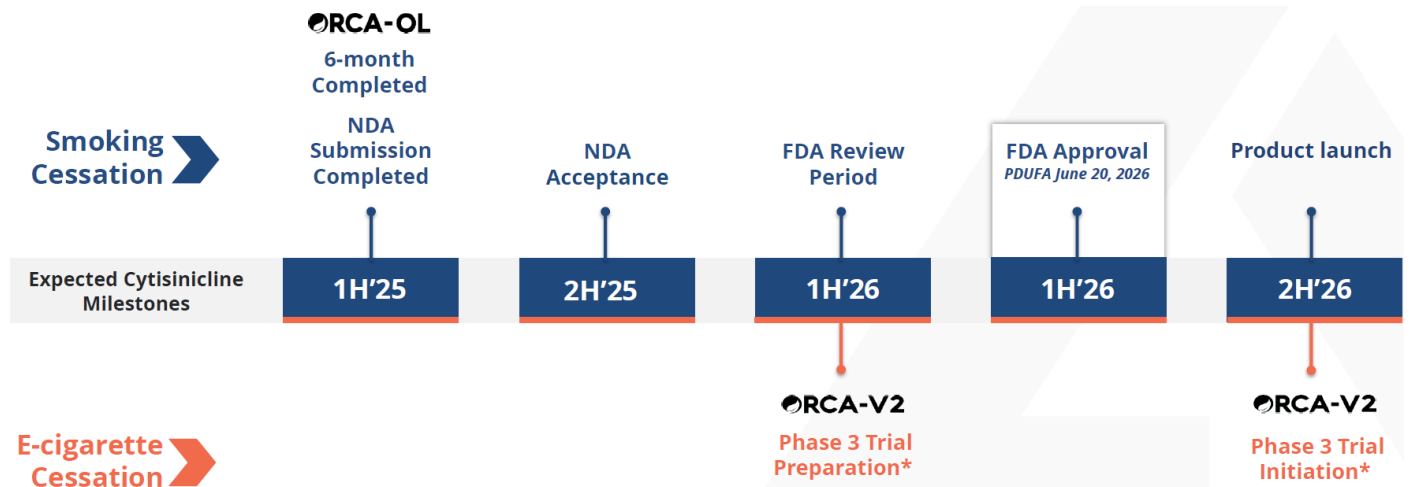
Achieve has identified several target groups for its marketing efforts that are stratified by age, social media use and other demographic data. It was able to identify these groups based on subject experiences in the company's many clinical trials. We anticipate that the structure of Achieve's internal 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 Xinos 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.

### 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
- Selection of 3<sup>rd</sup> party logistics partner – 2Q:25
- NDA Submission – 2Q:25
- BTIG Virtual Biotechnology Conference [attendance](#) – July 2025
- Anticipated acceptance of NDA by FDA – September 2025
- Attendance at HC Wainwright conference – September 2025
- Attendance at Lake Street Conference – 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 – June 20<sup>th</sup>, 2026
- Launch of cytisinicline – Late 2026

## Exhibit II – Achieve Development Timeline



### Summary

Achieve surpassed an important hurdle as the FDA accepts cytisinicline's NDA and assigns a PDUFA date of June 20<sup>th</sup>, 2026. The company also raises two internal employees to CMO and COO, strengthening the team as it advances towards commercialization. The Achieve team is on the road, sharing the investment thesis with stakeholders, specifically with investors at the Lake Street and HC Wainwright conferences in New York. We expect to hear updates on progress and details on the submission of one-year safety data during the third quarter conference call expected in mid-November.

## PROJECTED FINANCIALS

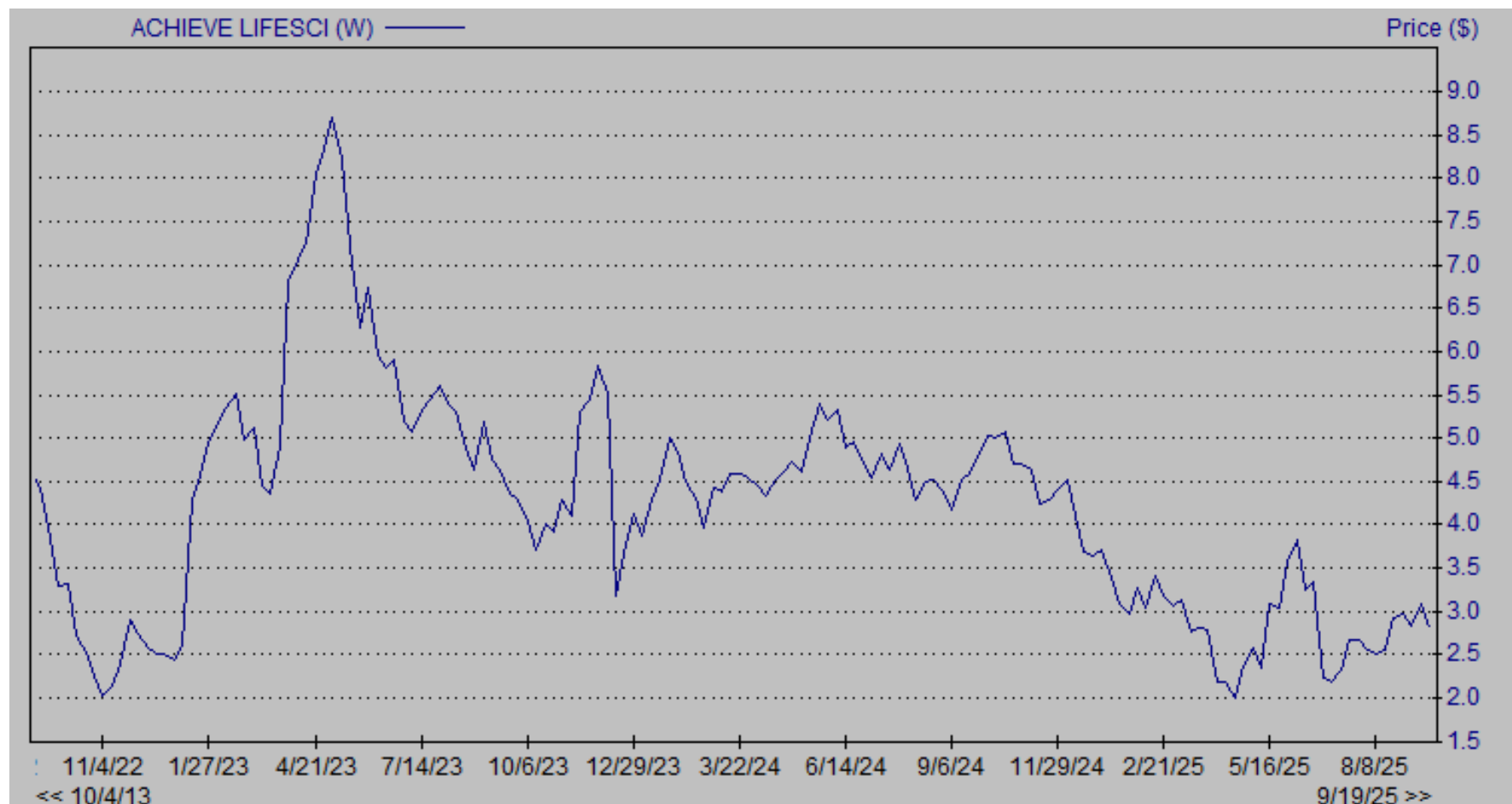
### Achieve Life Sciences, Inc. - Income Statement

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
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)	(\$0.3)	\$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
Tax Rate	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
YOY Growth								
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 Chart<sup>1</sup>



<sup>1</sup> Source: Zacks Research System

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