August 11, 2026

Achieve Life Sciences Reports Second Quarter 2026 Financial Results and Provides Business Updates

Closed a private placement of up to $354 million, with $180 million upfront and up to $174 million from warrants exercisable prior to and up to 20 trading days following FDA approval

Strengthened organization with new Chief Executive Officer, experienced commercial, CMC, and quality leaders, along with six new appointments to the Board of Directors

Anticipates potential FDA approval in the first half of 2027, followed by U.S. commercial launch

SEATTLE and VANCOUVER, British Columbia, Aug. 11, 2026 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Achieve or the Company) (Nasdaq: ACHV), a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline as a treatment for nicotine dependence, today announced financial results for the second quarter of 2026 and provided business updates.

“This quarter was about building Achieve to match the significant opportunity of cytisinicline,” said Andrew D. Goldberg, MD, Chief Executive Officer of Achieve. “We added a commercial team, senior CMC and quality leadership, six new directors, and advanced the finished drug product manufacturing transition to the United States. The Complete Response Letter raised no question about the efficacy or clinical safety of cytisinicline. With the team and financing in place, our focus turns to resubmission and commercial readiness. Behind that work are millions of adults still looking for help to quit.”

Key Highlights:

Regulatory Update

- On June 20, 2026, Achieve received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for cytisinicline, an outcome the Company disclosed it anticipated in April 2026. The CRL

relates to outstanding current Good Manufacturing Practice (cGMP) observations from an inspection of the Company's prior third-party manufacturing facility, which received an Official Action Indicated classification, and to final product labeling that was not completed by the FDA's action date. The FDA identified no deficiencies related to the clinical efficacy or safety of cytisinicline.
- Announced the transition of finished drug product manufacturing of cytisinicline to U.S.-based Adare Pharma Solutions (Adare). The Company has completed analytical method technology transfer, manufactured its first cytisinicline engineering batch, and fully qualified testing procedures at Adare's facility. The Company intends to resubmit its NDA naming Adare as its finished drug product manufacturer for commercial supply in the fourth quarter of 2026 and anticipates potential FDA approval in the first half of 2027, with U.S. commercial launch to follow.

Leadership and Board Updates

- Strengthened the Board of Directors with the appointments of Lucian Iancovici, MD (Managing Director, TPG), Aaron E. Royston, MD (Managing Partner, venBio), Christopher Martin (former Chief Commercial Officer, Verona Pharma), Jeffrey Farrow (CFO and CSO, Tarsus Pharmaceuticals), and Reid Waldman, MD (Founder and CEO, Veradermics), bringing combined expertise across healthcare investing, biopharmaceutical finance, and clinical-stage leadership. Dr. Goldberg also joined the Board in connection with his appointment as Chief Executive Officer.
- Announced commercial buildout with Mark Zappia and Jim Willis joining as Senior Vice President, Commercial, and Vice President of Sales and Sales Enablement, respectively, both previously part of the commercial launch team for Ohtuvayre® (ensifentrine) at Verona Pharma.
- Continued the finished drug product manufacturing transition with the appointments of Ronald Dadino as Senior Vice President, CMC and Supply Chain, and Gloria Cosgrove as Senior Vice President, Global Quality, each bringing significant U.S.-based pharmaceutical manufacturing and quality experience.

Scientific Data Advancement

- Presented 52-week safety data from the ORCA-OL study at the American Thoracic Society (ATS) 2026 Annual Meeting, completing the anticipated clinical evidence package supporting the cytisinicline NDA. Among 475 participants dosed for up to 52 weeks (median cumulative exposure of 361 days), no new safety signals were identified by the independent Data Safety Monitoring Committee.
- Presented analysis of ORCA-2 and ORCA-3 Phase 3 RCTs evaluating cytisinicline in participants with a baseline history of cancer at the American Society of Clinical Oncology (ASCO) 2026 annual meeting. Cytisinicline was well tolerated and showed numerically higher abstinence rates than placebo in this population (24.4% with 12 weeks of cytisinicline versus 15.8% with placebo).

Capital Raise

- Closed a private placement of up to $354 million ($180 million upfront; up to $174 million from milestone-based warrants exercisable prior to, and up to 20 trading days following, FDA approval of cytisinicline). Proceeds are expected to fund the ORCA-V2 Phase 3 trial, the commercialization of cytisinicline, and working capital and general

corporate purposes.

Financial Results
As of June 30, 2026, the Company's cash, cash equivalents, and marketable securities were $187.3 million. Total operating expenses for the three and six months ended June 30, 2026, were $18.4 million and $28.9 million, respectively. Total net loss for the three and six months ended June 30, 2026, was $74.8 million and $84.9 million, respectively. Net loss for the quarter includes a non-cash charge of $48.7 million related to the change in fair value of the warrant liabilities issued in connection with the Company's private placement.

Investor Communications
Achieve will host conference calls in connection with significant clinical, regulatory, and commercial milestones, including the planned resubmission of the NDA for cytisinicline. Management will continue to participate in investor meetings and industry conferences.

About Achieve Life Sciences, Inc.
Achieve Life Sciences, Inc. is a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline as a treatment for nicotine dependence. Achieve's New Drug Application (NDA) for cytisinicline for smoking cessation in adults is supported by two successfully completed Phase 3 studies and an open-label long-term safety study. Achieve has also completed a Phase 2 study of cytisinicline in nicotine e-cigarette cessation, conducted an end-of-Phase 2 meeting with the FDA, and has received Breakthrough Therapy designation for the vaping cessation indication.

About Cytisinicline
There are approximately 25 million adults in the United States who smoke combustible cigarettes, and tobacco use is currently the leading cause of preventable death.[1,2]

In addition, there are nearly 18 million adults in the United States who use e-cigarettes, also known as vaping.[1] In 2025, approximately 1.4 million middle and high school students in the United States reported using e-cigarettes.[3] There are no FDA-approved treatments indicated specifically as an aid to nicotine e-cigarette cessation. FDA has awarded the Commissioner's National Priority Voucher for e-cigarette or vaping cessation and granted Breakthrough Therapy designation to address this critical need.

Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in treating nicotine addiction for smoking and e-cigarette cessation by interacting with nicotine receptors in the brain, reducing the severity of nicotine craving symptoms, and reducing the reward and satisfaction associated with nicotine products.

Forward Looking Statements
This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements Achieve makes regarding the timing, nature and outcome of cytisinicline clinical development and regulatory review and approval, data results, the timing, nature and success of Achieve's commercialization activities, the potential market size for cytisinicline, the potential benefits, efficacy, safety and tolerability of cytisinicline, the development and effectiveness of new treatments, the performance of Achieve's third-party manufacturing partners, the successful launch and commercialization of cytisinicline, the use of proceeds from Achieve's private placement, and statements concerning Achieve Life

Sciences' future plans and prospects. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Achieve may not actually achieve its plans or product development goals in a timely manner, if at all, or otherwise carry out its intentions or meet its expectations or projections disclosed in these forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including those described in Achieve's Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q. Achieve undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable law.

Achieve Contact
Nicole Jones
VP, Strategic Communications and Stakeholder Relations
ir@achievelifesciences.com
425-686-1510

References

[1]Agaku I. Tobacco Product Use among U.S. Adults, 2023–2024, NEJM Evidence, doi: 10.1056/EVIDpha2500339.
[2]World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2019.
[3]Eunice Park-Lee, Lauren M Dutra, Hannah Cowan, et al. Tobacco Product Use Among Middle and High School Students in the United States: National Youth Tobacco Survey, 2025, *Nicotine & Tobacco Research*, 2026; ntag116, doi.org/10.1093/ntr/ntag116.

Consolidated Statements of Loss
(In thousands, except per share and share data)

	Three months ended June 30,		Six months ended June 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	3,808	6,707	7,100	13,804
General and administrative	14,584	5,856	21,755	11,653
Total operating expenses	18,392	12,563	28,855	25,457
Loss from operations	(18,392)	(12,563)	(28,855)	(25,457)
Other income	(56,377)	(155)	(56,082)	(88)
Net loss	$ (74,769)	$ (12,718)	$ (84,937)	$ (25,545)
Basic and diluted net loss per share	$ (0.80)	$ (0.37)	$ (1.15)	$ (0.74)

Weighted average number of basic and diluted common shares	93,510,544	34,685,072	73,557,119	34,685,072

Consolidated Balance Sheets
(In thousands)

	June 30, 2026	December 31, 2025
Assets:		
Cash, cash equivalents and marketable securities	$ 187,303	$ 36,404
Prepaid expenses and other current assets	991	3,485
Other assets and restricted cash	268	52
Right-of-use assets	34	64
Other intangible assets	169	—
License agreement	640	751
Goodwill	1,034	1,034
Total assets	$ 190,439	$ 41,790
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 5,416	$ 3,760
Current portion of long-term obligations	36	61
Current portion of convertible debt	7,454	3,704
Contingent consideration	1,372	1,557
Warrant and pre-funded warrant liability	183,379	—
Non-current portion of convertible debt	7,458	11,185
Other long-term obligations	—	5
Stockholders' equity	(14,676)	21,518
Total liabilities and stockholders' equity	$ 190,439	$ 41,790

Source: Achieve Life Sciences