April 28, 2026

Zacks Small-Cap Research (NOTE)

Sponsored – Impartial - Comprehensive

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: Change of Command Brings Material Funding

Research Note

Achieve Life Sciences, Inc. (NASDAQ: ACHV) generated significant news flow in April, announcing the arrival of a new CEO, substantial new financing and a cytisinicline manufacturing update. On April 15th, Achieve indicated that it had completed cytisinicline's technology transfer to Adare Pharma Solutions in Vandalia, Ohio. The shift in manufacturers sought to address inspection discrepancies at Achieve's prior manufacturer and the risk of tariffs on foreign-produced products. The next day, Andrew Goldberg was introduced as CEO and a private placement was announced that could raise up to $354 million. In the preceding weeks, investors had raised concerns that a delay in approval could lead to further dilution. With the capital raise, this concern has been meaningfully reduced.

Shift to Adare Pharma Solutions

Manufacturing Modifications

Along with its 2025 earnings report released on March 24th, Achieve announced that it had developed a partnership with Adare Pharma Solutions, a domestic manufacturer of drug products. In a follow-up release, Achieve indicated that the unnamed manufacturer listed in its new drug application (NDA) had received two observations related to solid oral dose manufacturing. In a press release on April 15th, 2026, the company indicated that the FDA had issued an Official Action Indicated (OAI) classification to that unnamed manufacturer following a current Good Manufacturing Practices (cGMP) inspection.[1] The OAI arose from general cGMP matters not related to cytisinicline. As a result, management believes that the FDA will issue a Complete Response Letter (CRL) for cytisinicline.

The relationship with Adare helps diversify manufacturers, source domestically to avoid tariffs and sidestep the problematic OAI classification. Adare's manufacturing facility is located in Vandalia, Ohio and significant progress has been made transferring cytisinicline manufacturing there. Achieve has completed the analytical transfer and has confirmed that the first cytisinicline engineering batch has been manufactured. Adare's Chief Executive, Tom Sellig, the CEO of Adare, sits on Achieve's board of directors, providing a connection that should support rapid progress, communication and execution.

Investor Sentiment

Following the report of 2025 results, investors raised concerns regarding a CRL from the FDA due to the observations that were noted in the 2025 Form 10-K. Beyond the impact of a commercialization delay, the concerns centered on the anticipated funding gap that would arise due to the shift of commercialization efforts into 1H:27. These concerns were meaningfully addressed by the $180 million capital raise that Achieve successfully completed. In the days after the raise, the market responded positively and shares rose from around $3.50 to over $4.00 per share indicating favorable sentiment with respect to the financing and management change.

[1] An official action indicated (OAI) means regulatory and/or administrative actions are recommended. An OAI finding may result in warning letters, enforcement actions, or follow-up inspections. In clinical research, OAI classifications often relate to informed consent deficiencies, protocol noncompliance, or inadequate recordkeeping. Organizations must implement documented corrective and preventive actions (CAPA) to remediate issues.

© Copyright 2026, Zacks Investment Research. All Rights Reserved.

New Executive and Board Members Added

New CEO Andrew Goldberg, MD, assumed the top spot at Achieve and was added to the company's board of directors. Two other directors joined the board along with Dr. Goldberg, including Lucian Iancovici, MD a managing director at TPG and Aaron Royston, MD a managing partner at venBio. Dr. Goldberg's bio highlights his experience as portfolio manager and partner as well as his experience as board member at numerous life sciences companies. See the following paragraph for further details.

Andrew D. Goldberg, MD, was appointed Chief Executive Officer of Achieve Life Sciences in April 2026. Dr. Goldberg is a physician, healthcare investor and governance leader who has spent his career at the intersection of clinical medicine and commercial execution. Most recently, he served as a Portfolio Manager at Marshall Wace and previously as a Partner at Vivo Capital, a healthcare-focused investment firm. Earlier in his career, he was a consultant at McKinsey & Company in Silicon Valley, advising pharmaceutical, biotechnology, and medical device companies. He has served as a board director or observer at 19 life sciences companies, including Tarsus Pharmaceuticals (TARS) through FDA approval and the national launch and commercialization of XDEMVY, Veradermics (MANE) through its successful IPO, Inquis Medical through FDA approval and commercialization of the Aventus thrombectomy system, Elektrofi through its $900M acquisition by Halozyme Therapeutics (HALO), Parse Biosciences through its acquisition by Qiagen (QGEN), and Forge Biologics through its acquisition by Ajinomoto. As lead investor, he anchored the U.S. market transition for Verona Pharma (VRNA), culminating in the $10.8B acquisition by Merck, and led the pre-IPO investment in Harmony Biosciences (HRMY), which scaled WAKIX into a new category in sleep medicine. Dr. Goldberg is among the first physicians in the United States to earn dual board certification in Critical Care Medicine and Emergency Medicine. He served as an Instructor in Medicine at the Mayo Clinic, where he completed a Critical Care fellowship, after training in Emergency Medicine at LAC+USC. He has over 25 scientific publications including research on tobacco advertising, published in JAMA, that examined youth targeting and contributed to public-health initiatives that earned him the Oregon Governor's Council Outstanding Achievement Award. Dr. Goldberg received his MD from The George Washington University School of Medicine and a post-doctoral diploma in translational science from the Mayo Graduate School.

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 exercisable within 20 days of FDA approval. If cytisinicline is successfully approved, this structure will generate the capital the company needs 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 will expire 20 business days after FDA approval of cytisinicline for smoking cessation or two years after shareholder approval is given for an increase in the number of authorized shares of common stock.

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 participating in the deal include Frazier Life Sciences, TPG Life Sciences Innovations, venBio Partners, Paradigm BioCapital Advisors and Marshall Wace and also includes 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

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 to serve as the company's supplier and earlier this year the FDA conducted a non-Achieve related cGMP inspection which made two observations related to solid oral dose manufacturing. This was reported in the 2025 Form 10-K filed in March. A follow-up press release on April 15th, 2026 reported that the FDA issued an OAI classification from the inspection. As a result, Achieve expects to receive a Complete Response Letter (CRL) from the FDA before the June 20th

PDUFA date. Another New Drug Application (NDA) listing Adare as manufacturer is expected to be submitted as soon as feasible.

When a CRL is issued the review clock resets after the drug sponsor addresses the deficiencies. There are two types of submissions. A Class 1 Resubmission is for minor changes and the FDA targets a response within two months. A Class 2 Resubmission is for major changes and can take six months to review.

Based on our experience with CRLs, a 2-month review is possible if the FDA is comfortable with the Adare site, but it is more likely that a new manufacturing facility will require an Achieve-specific inspection. In the latter case, a six-month review is expected.[2] We expect management will provide additional detail on expectations in its first quarter 2026 conference call.

Publication in Nicotine & Tobacco Research

A March 26th, 2026 press release informed stakeholders of the publication of "Receptor Selectivity of Cytisinicline: Minimal 5-HT3 Binding May Explain Lower Incidence of Nausea in Smoking Cessation Therapy." The paper provided detail derived from preclinical studies to show the mechanism of action of cytisinicline. The alkaloid compound acts as a selective partial agonist at α4β2 nicotinic acetylcholine receptors in the brain. It binds to the nicotinic receptor but only has minimal interaction with the serotonin receptor which is associated with nausea. Other smoking cessation products such as varenicline do bind to serotonin receptors such as 5-HT3. Side effects of serotonin receptor binding to 5-HT3 include headache, dizziness, constipation, diarrhea, fatigue/malaise, drowsiness, and occasional nausea-related or gastrointestinal complaints.

The article found that cytisinicline demonstrated strong binding at the α4β2 nicotinic receptor, displacing nearly all (99%) of the comparison compound in laboratory testing. This high level of receptor engagement suggests cytisinicline effectively targets the mechanism associated with smoking cessation. It also identified minimal 5-HT3 receptor displacement. At the same concentration, cytisinicline showed minimal displacement (-8%) at the 5-HT3 receptor, indicating negligible binding under assay conditions. This minimal interaction is significant as activation of the 5-HT3 receptor is known to induce nausea, which helps explain cytisinicline's tolerability profile observed in clinical trials.

These findings may explain the higher compliance rates for subjects using cytisinicline compared with varenicline. They explain the lower nausea rates observed in clinical trials and highlight cytisinicline as an attractive alternative for individuals sensitive to medication-related side effects. The drug's receptor-specific profile may enhance treatment adherence and expand the appeal of pharmacologic smoking cessation strategies.

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."

[2] One example of a manufacturing deficiency Novartis' submission of Inclisiran in 2020. The original site had unresolved inspection-related conditions. Novartis changed the site which required new validation, inspection readiness and CMC updates for its resubmission. It was considered a Class 2 resubmission and received a six month review.

Milestones

- NDA Submission – 2Q:25
- 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
- Award of CNPV for cytisinicline in a vaping indication – October 2025
- ICER publishes evidence report for cytisinicline – December 2025
- Appointment of Dr. Mark Rubinstein as Chief Medical Officer – January 2026
- Publication in Thorax journal: Cytisinicline for Smoking Cessation – February 2026
- Manufacturing partnership announced with Adare Pharma – March 2026
- Publication in Nicotine & Tobacco Research – March 2026
- Appointment of Andrew Goldberg as CEO – April 2026
- Private placement – April 2026
- Presentation at American Thoracic Society Conference – May 2026
- Phase III ORCA-V2 vaping trial initiation – 2026
- FDA target action date for cytisinicline NDA – June 20th, 2026
- Launch of cytisinicline – 1H:27

Summary

Several press releases beginning mid-April announced material news items for Achieve that brings new management, capital and partners to the company. The releases also indicate that management anticipates a CRL to be issued for the New Drug Application for cytisinicline prior to the assigned PDUFA date. While this risk initially concerned investors, the capital raise, the extended runway and the confidence provided by a consortium of investors involved in the deal has minimized the apprehension. A new CEO with extensive deal experience now takes over and is expected to transition the company from a development to a commercialization firm. We look forward to first quarter earnings report in a few weeks where we expect to hear from the new leadership and gain additional detail about the path forward.

DISCLOSURE

SUBSCRIBE TO ZACKS SMALL CAP RESEARCH to receive our articles and reports emailed directly to you each morning. Please visit our website for additional information on Zacks SCR.

DISCLOSURE: Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm, engaged by the issuer, for providing research coverage for a period of no less than one year. Research articles, as seen here, are part of the service Zacks provides and Zacks receives payments for these services. Full Disclaimer HERE.