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Achieve Life Sciences, Inc. (ACHV: NASDAQ)

ACHV: CEO Enlists New Commercialization Team

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 (5/12/2026)	$5.99
Valuation	**$21.00**

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 results demonstrating attractive safety & efficacy. Achieve expects a complete response letter (CRL) for its NDA submission due to issues at its former manufacturer. It plans a resubmission in 4Q:26. While waiting for approval, the company is focused on pre-commercialization activities guided by Omnicom and its family of businesses.

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 from 25 to 30 million smokers in the US and over 1 billion globally, providing a substantial population demanding an improved smoking cessation product. We anticipate a 1H:27 commercialization of cytisinicline.

A pivotal vaping trial is planned for 2026. The vaping indication has been awarded a CNPV, which will accelerate the approval timeline but must be used within two years of grant.

OUTLOOK
SUMMARY DATA

52-Week High	**6.15**
52-Week Low	**2.00**
One-Year Return (%)	**141.5**
Beta	**2.3**
Average Daily Volume (sh)	**1,062,848**
Shares Outstanding (mil)	**102.7**
Market Capitalization ($mil)	**615.4**
Short Interest Ratio (days)	**4.2**
Institutional Ownership (%)	**62.6**
Insider Ownership (%)	**0.9**
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 2026 Estimate	**N/A**
P/E using 2027 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)
2025	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2026	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2027					$20.7 E
2028					$107.1 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2025	-$0.37 A	-$0.37 A	-$0.28 A	-$0.28 A	-$1.25 A
2026	-$0.19 A	-$0.21 E	-$0.21 E	-$0.26 E	-$0.89 E
2027					-$0.44 E
2028					$0.10 E

WHAT'S NEW

Achieve Life Sciences, Inc. (NASDAQ: ACHV) reported first quarter results following the recent appointment of Dr. Andrew Goldberg as CEO and a material capital raise. In its report, management reiterated expectations that it will receive a Complete Response Letter (CRL) and affirmed its intent to resubmit a New Drug Application (NDA) in 4Q:26. If Achieve is able to hold this timeline, it should support a 1H:27 launch of cytisinicline in smoking cessation. Along with first quarter results, the company announced several changes to the board including the appointment of a new Chairman and new leadership in the commercialization team. The new professionals bring experience gained at Verona Pharma. They launched Ohtuvayre in 2024 which is estimated to be an $800 million drug this year.

As previously mentioned, Adare Pharma Solutions will be Achieve's primary manufacturer for cytisinicline. It has completed the technology transfer, successfully manufactured its first cytisinicline engineering batch and fully qualified all testing procedures at the facility. Achieve announced the shift to Adare in March citing the domestic location of the manufacturer, the avoidance of tariffs and the Official Action Indicated (OAI) classification at its European manufacturer as reasons for the change.

Financial and Operational Results

Achieve's 1Q:26 financial and operational results were detailed in a press release, Form 10-Q filing and webcast, which provided analysts the opportunity to ask questions. No revenues were reported in 1Q:26. Operating expense was $10.5 million producing a net loss of $10.2 million or $0.19 per share. For the quarter ending March 31st, 2026 versus the same prior year period:

- Research & development expense totaled $3.3 million, down 54% from $7.1 million, due to lower clinical trial costs and stock-based compensation. This was partially offset by higher manufacturing and supply chain costs related to the anticipated commercial launch. These costs included the purchase of raw cytisinicline inventory and the technology transfer to Adare;
- General & administrative expense was $7.2 million, up 24% from $5.8 million on higher legal expenses, employee expenses and commercial launch preparation. These were partially offset by a decrease in stock-based compensation expenses;
- Net interest income was $23,000 vs. $137,000 as greater debt balances offset interest income;
- Other expense of $0.3 million was related to change in fair value of contingent consideration and other expense;
- Net loss was $10.2 million vs. $12.8 million or $0.19 and $0.37 per share, respectively.

As of March 31st, 2026, cash and equivalents totaled $29.3 million. This compares to a $36.4 million balance held at the end of 2025. At the end of the first quarter, Achieve carried convertible debt of $14.9 million on the balance sheet. Cash used in operations during 1Q:26 was $6.9 million versus $11.1 million in the same prior year period. Following the end of the first quarter, on April 16th, 2026, Achieve announced a $180 million financing that was funded by a consortium of healthcare investors. It included warrants that could raise another $174 million upon FDA approval of cytisinicline. Based on management guidance, this approval could come in the first half of 2027.

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. Announced alongside first quarter results, Dr. Iancovici was elevated to the role of Chairman of the Board and Christopher Martin was added to the board.

Other members were added to the executive team to strengthen the commercialization effort. Mark Zappia joined as Senior Vice President, Commercial and Jim Willis joined as Vice President of Sales and Sales Enablement where he will lead the field force. These individuals were part of the team at Verona Pharma where they led the commercial operations for the launch of Ohtuvayre, a therapy for chronic obstructive pulmonary disease (COPD) which has generated almost $550 million in revenues over the trailing four quarters and is expected to generate over $800 million in 2026.[1]

[1] Estimates sourced from Evaluate, Ltd.

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 the unnamed manufacturer following a current Good Manufacturing Practices (cGMP) inspection.[2] Achieve management asserts that the OAI arose from general cGMP matters not related to cytisinicline. As a result, it believes that the FDA will issue a CRL for cytisinicline.

The relationship with Adare helps 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, sits on Achieve's board of directors, providing a connection that should support rapid progress, communication and execution.

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 for cytisinicline. Earlier this year, the FDA conducted a non-Achieve related cGMP inspection at their facility 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 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 resubmissions. A Class 1 Resubmission is for minor changes where the FDA targets a response within two months. A Class 2 Resubmission is for major changes and can take six months to review.

[2] 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.

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.[3] Management has promised to update us on the anticipated regulatory route when it is closer to resubmission.

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 help explain the higher compliance rates for subjects using cytisinicline compared with varenicline. They provide a rationale for 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 authors observed 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 analysis found 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."

[3] 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.

SRNT Presentation

Achieve presented new data at the Society for Research on Nicotine & Tobacco (SRNT) 2026 Annual Meeting, held from March 4-7 in Baltimore, Maryland. Information was presented at two sessions drawing from participants in the ORCA-OL and the more than 1,600 participants in the ORCA-2 and ORCA-3 studies. Titles of the sessions and conclusions are included below.

- Cytisinicline in Adult Smokers: Post-Trial Survey from ORCA-OL
  - Many individuals do not complete a smoking cessation course of therapy due to side effects and patient experience is important to success
  - Participants reported better physical health while taking cytisinicline including improved breathing, increased stamina and greater vitality
  - Participants were satisfied with cytisinicline reporting that the urge to smoke had lessened, and fewer psychological cravings
  - Cytisinicline was well tolerated even with up to one year of use with no new safety signals during the open label phase
- Efficacy of Cytisinicline for Smoking Cessation in Adults with and without Multiple Prior Quit Attempts or Prior Pharmacotherapy Use: Pooled Analysis of Two Phase 3 Trials
  - The presentation concluded that cytisinicline was effective and well-tolerated regardless of participants' prior use of smoking cessation medications or number of previous quit attempts
  - If approved in the US, cytisinicline will offer a new quit option for patients, including those who have failed other medications
  - Cytisinicline was consistent across regimens with benefits observed for both the six- and twelve-week treatment courses, although the twelve-week course provided improved long-term outcomes

Milestones

- FDA awards Commissioner's National Priority Voucher (CNPV) for vaping indication – October 2025
- Appointment of Dr. Mark Rubinstein as Chief Medical Officer – January 2026
- Publication in Thorax journal: Cytisinicline for Smoking Cessation – February 2026
- Presentation at Society for Research on Nicotine & Tobacco (SRNT) meeting – March 2026
- Manufacturing partnership announced with Adare Pharma – March 2026
- Publication in Nicotine & Tobacco Research – March 2026
- Technology transfer to Adare – April 2026
- Appointment of Andrew Goldberg as CEO – April 2026
- Private placement – April 2026
- Appointment of new board member and commercialization executives – May 2026
- Presentation at the American Thoracic Society Conference – May 2026
- Phase III ORCA-V2 vaping trial initiation – 2026
- Resubmission of cytisinicline NDA for smoking cessation – 4Q:26
- FDA approval of cytisinicline for smoking cessation – 1H:27
- Launch of cytisinicline – 1H:27

Valuation

We adjust our valuation to reflect the April 16th capital raise and the additional shares expected to be issued over the next 18 months. Furthermore, we move our estimated first sales to 2027 from 2026 and advance our NPV cash flow model ahead by one year. With the addition of skilled operators that were fundamental to the launch of Verona's Ohtuvayre, which is forecast to exceed $1.3 billion[4] in sales next year, we also increase our revenue estimates for cytisinicline. The result of these changes generates a valuation of $21 per share.

[4] Estimates sourced from Evaluate, Ltd.

Summary

First quarter 2026 results gave Achieve's newly appointed CEO an opportunity to speak directly to investors and provide the broad outlines of the company's next steps. Over the last weeks, Achieve has added a highly experienced and energetic team to the company's board and senior ranks with experience launching critical medicines and potentially preparing them to be acquired by the most established pharmaceutical companies.

The first quarter report did not provide firm details on the status of the NDA that was submitted last year, but it did reiterate the expectation of a CRL and outline the expected milestones over the next four quarters. We should see further interaction with the FDA, the issuance of a CRL, the launch of the vaping trial and an NDA resubmission before year end. These activities prime Achieve to receive FDA approval for cytisinicline by 1H:27 and a launch of the smoking cessation product shortly after.

Achieve has been busy presenting the data and conclusions from its ORCA trials at several conferences and publications. This is expected to increase awareness of the product and its attractive safety and efficacy profile compared with other alternatives such as varenicline. We believe the outreach will support increased scientific credibility, greater awareness among prescribers, position cytisinicline for commercial advantage and improve investor confidence in the product.

We update our valuation to reflect the recent capital raise and new shares expected to be issued over the next 18 months. We also raise our revenue estimates based on our confidence in an experienced team that launched what is soon expected to be a $1 billion+ product in COPD. To reflect these changes, we update our valuation to $21 per share.

PROJECTED FINANCIALS

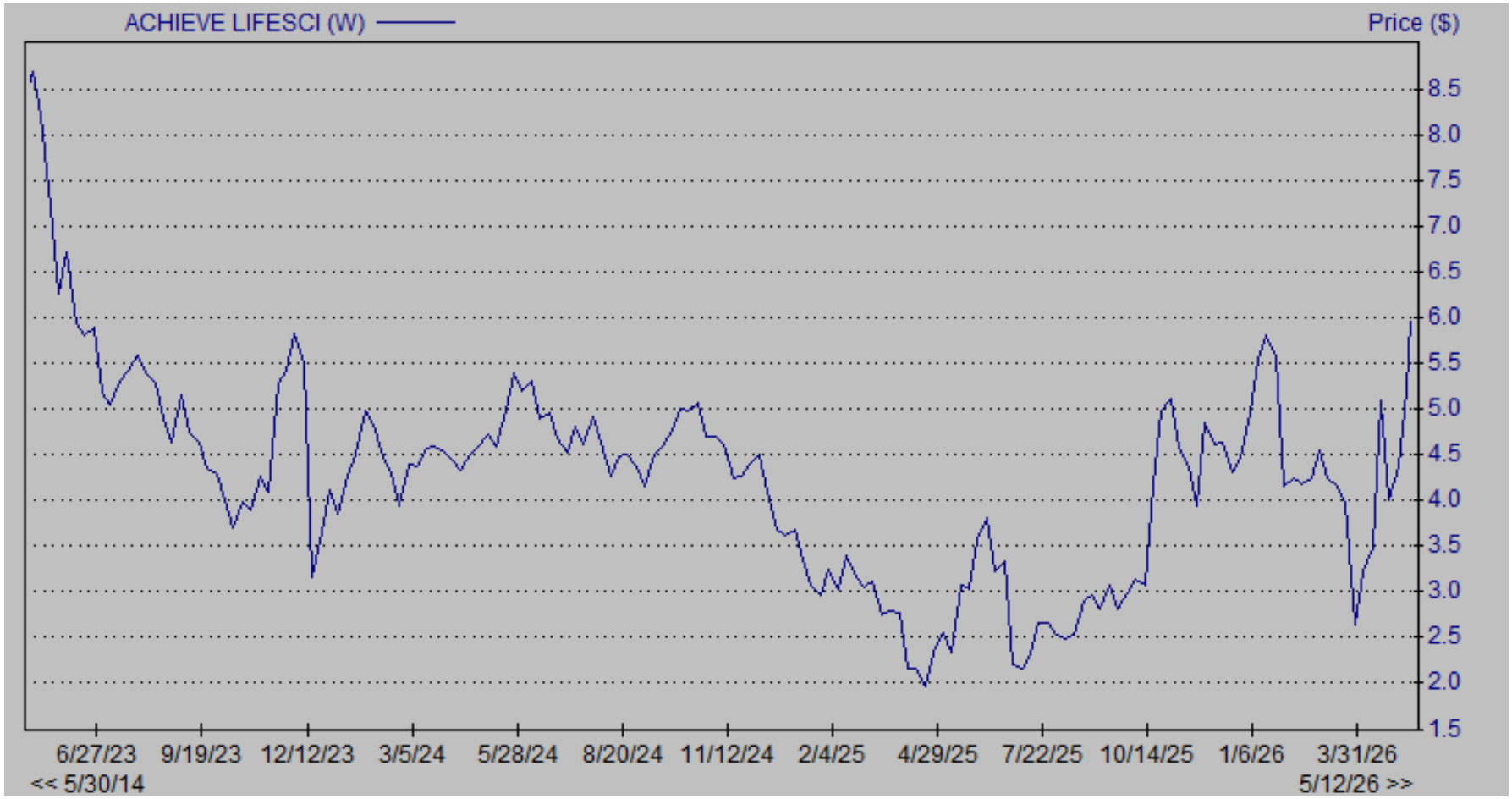
Achieve Life Sciences, Inc. - Income Statement

Achieve Life Sciences, Inc.	2025 A	Q1 A	Q2 E	Q3 E	Q4 E	2026 E	2027 E	2028 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$20.7**	**$107.1**
Growth	-					-		517%
R&D	$23.0	$3.3	$4.0	$8.0	$9.0	$24.3	$20.0	$15.0
G&A	$31.9	$7.2	$10.5	$14.2	$18.0	$49.9	$29.6	$30.2
S&M	$0.0						$31.5	$42.0
Operating Income	($54.9)	($10.5)	($14.5)	($22.2)	($27.0)	($74.2)	($60.3)	$19.9
Operating Margin							*-291.2%*	*18.6%*
Interest Income	$0.7	$0.0	$0.1	$0.1	$0.1	$0.3	$0.8	$0.2
Total Other Income	($0.4)	$0.3	$0.0	$0.0	$0.0	$0.3	$0.0	$0.0
Pre-Tax Income	($54.6)	($10.2)	($14.4)	($22.1)	($26.9)	($73.6)	($59.5)	$20.1
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	($54.7)	($10.2)	($14.4)	($22.1)	($26.9)	($73.6)	($59.5)	$20.1
	0%							
Reported EPS	**($1.25)**	**($0.19)**	**($0.21)**	**($0.21)**	**($0.26)**	**($0.89)**	**($0.44)**	**$0.10**
Shares Outstanding	43.6	53.4	69.4	103.1	104.5	82.6	136.9	200.0

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

HISTORICAL STOCK PRICE

Achieve Life Sciences, Inc. – Stock Price Chart[5]



[5] Source: Zacks Research System

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