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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934  
Date of Report (Date of earliest event reported): December 11, 2023

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**ACHIEVE LIFE SCIENCES, INC.**  
(Exact name of Registrant as Specified in Its Charter)

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<b>Delaware</b> (State or Other Jurisdiction of Incorporation)	<b>033-80623</b> (Commission File Number)	<b>95-4343413</b> (IRS Employer Identification No.)
<b>22722 29th Drive SE, Suite 100</b> <b>Bothell, WA</b>		<b>98021</b>
<b>1040 West Georgia, Suite 1030</b> <b>Vancouver, BC, Canada</b> (Address of Principal Executive Offices)		<b>V6E 4H1</b> (Zip Code)

**Registrant's Telephone Number, Including Area Code: (604) 210-2217**

N/A  
(Former Name or Former Address, if Changed Since Last Report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of exchange on which registered</u>
Common Stock, par value \$0.001 per share	ACHV	The Nasdaq Capital Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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## Item 8.01 Other Events.

As previously reported, Achieve Life Sciences, Inc. (the “Company”) recently conducted a pre-New Drug Application (“NDA”) meeting with the U.S. Food and Drug Administration (“FDA”) for the Company’s drug product candidate, cytisinicline, during which agreement was reached on many of the submission requirements for an NDA. During that meeting, the FDA expressed support for an NDA submission based on adequate data to assess efficacy from the two randomized and controlled Phase 3 trials. In addition, the FDA advised that long-term exposure data beyond 12 weeks would be needed to adequately assess safety risk given that it views smoking cessation drugs as products for chronic, intermittent use because patients may relapse and require subsequent courses of treatment over a lifetime. The FDA advised that long-term safety data could be collected on a patient’s cumulative treatment over time and could also be collected in the vaping cessation program. The Company is participating in ongoing discussions with the FDA to clarify the requirements and timing for the long-term exposure safety data to support an NDA submission and the Company’s NDA filing timing may be delayed to address this FDA feedback. Following receipt of additional input from the FDA, anticipated in the first quarter of 2024, the Company will provide an update on its projected NDA submission timing.

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This Current Report on Form 8-K 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 regarding the timing of planned clinical development activities of cytisinicline and interactions with the FDA, and the projected path toward potential regulatory approval. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The Company may not actually achieve its plans or product development goals in a timely manner, if at all, or otherwise carry out the intentions or meet the 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, among others, general business and economic conditions, including inflation, rising interest rates, increased volatility in the debt and equity markets, instability in the global banking system, global health crises and pandemics and geopolitical conflict; the need for and ability to obtain additional financing; the risk that cytisinicline may not demonstrate the hypothesized or expected benefits; the risk that cytisinicline will not receive regulatory approval or be successfully commercialized; the risk that new developments in the smoking cessation landscape require changes in business strategy or clinical development plans; the risk that the Company’s intellectual property may not be adequately protected; other risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates that are safe and effective for use as human therapeutics; and the other factors described in the risk factors set forth in the Company’s filings with the Securities and Exchange Commission from time to time, including its Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q. The Company 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.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACHIEVE LIFE SCIENCES, INC.

Date: December 11, 2023

/s/ John Bencich

John Bencich

Chief Executive Officer (Principal Executive and Financial Officer)

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