## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM S-3 REGISTRATION STATEMENT

UNDER
THE SECURITIES ACT OF 1933

## ACHIEVE LIFE SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 95-4343413 (I.R.S. Employer Identification No.)

22722 29th Drive SE, Suite 100 Bothell, WA 98021 1040 West Georgia Street, Suite 1030 Vancouver, BC V6E 4H1 (604) 210-2217

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

John Bencich Chief Executive Officer Achieve Life Sciences, Inc. 22722 29th Drive SE, Suite 100 Bothell, WA 98021 (604) 210-2217

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Please send copies of all communications to:

Amanda Rose, Esq. Alan Smith, Esq. Chelsea Anderson, Esq. Fenwick & West LLP 401 Union Street, 5th Floor Seattle, WA 98101 (206) 389-4510

		(206)	389-4510		
		ne to time after this regis roximate date of commence			
If the only securities being	registered on this Form are b	eing offered pursuant to di	vidend or interest reinvest	ment plans, please check the following box. $\Box$	
	ng registered on this Form are y in connection with dividend			ant to Rule 415 under the Securities Act of 1933, other ox. ⊠	
	ster additional securities for a statement number of the earli			es Act, please check the following box and list the $\Box$	
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The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and it is not soliciting an offer to buy these securities, in any jurisdiction where the offer or sale is not permitted.

**SUBJECT TO COMPLETION. DATED JUNE 14, 2023** 

**PROSPECTUS** 



## 1,986,611 Shares of Common Stock

This prospectus relates to the registration for potential offer and sale from time to time of up to 1,986,611 shares of our common stock, par value \$0.001 per share (the "Shares"), by the selling stockholders to be identified in a prospectus supplement. The Shares registered hereunder consist of 1,986,611 shares issuable to the selling stockholders upon the conversion of \$18.6 million aggregate amount of outstanding indebtedness at a conversion price equal to \$9.34 per share, including accrued and unpaid interest, pursuant to the contingent convertible debt agreement with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company ("FCB"), in its capacity as administrative agent and collateral agent, FCB, as a lender, SVB Innovation Credit Fund VIII, L.P., as a lender, and Innovation Credit Fund VIII-A, L.P., as a lender. For more information regarding the Shares, see "Selling Stockholders" herein.

Prior to such time that the selling stockholders offer and sell Shares, we or such selling stockholders will provide a supplement to this prospectus that contains specific information about the selling stockholders. The supplement may also add, update or change information contained in this prospectus with respect to any offering of the Shares. You should carefully read this prospectus and the applicable prospectus supplement before you invest in our common stock.

The selling stockholders may sell the Shares directly to purchasers or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions. The selling stockholders may sell the Shares at any time at market prices prevailing at the time of sale or at privately negotiated prices. For more information regarding the selling stockholders and the sale of the Shares, see "Selling Stockholders" and "Plan of Distribution" herein.

We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of the Shares by the selling stockholders. We will pay the expenses incurred in registering the Shares, including legal and accounting fees.

Our common stock is traded on The Nasdaq Capital Market under the symbol "ACHV." On June 13, 2023 the last reported sales price for our common stock was \$5.98 per share.

Investing in our securities involves a high degree of risk. Before making any investment in these securities, you should consider carefully the risks and uncertainties in the section entitled "Risk Factors" beginning on page 5 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense. The securities are not being offered in any jurisdiction where the offer is not permitted.

The date of this prospectus is , 2023

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## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the United States Securities and Exchange Commission (the "SEC"). Under this registration process, the selling stockholders to be named in a supplement to this prospectus may, from time to time, sell or otherwise distribute the securities offered by them as described in the section titled "Plan of Distribution" in this prospectus. Prior to such time that the selling stockholders offer and sell Shares, we or such selling stockholders will provide a supplement to this prospectus that contains specific information about the selling stockholders. The supplement may also add, update or change information contained in this prospectus with respect to any offering of the Shares. You should carefully read this prospectus and the applicable prospectus supplement before you invest in our common stock. We will not receive any proceeds from the sale by such selling stockholders of the securities offered by them described in this prospectus.

Neither we, the selling stockholders, nor any agent, underwriter or dealer have authorized anyone to give you any information or to make any representation other than the information and representations contained in or incorporated by reference into this prospectus or any applicable prospectus supplement. We, the selling stockholders and any agent, underwriter or dealer take no responsibility for, and can provide no assurance as to the reliability of, any other information others may give you. You may not imply from the delivery of this prospectus and any applicable prospectus supplement, nor from a sale made under this prospectus and any applicable prospectus supplement, that our affairs are unchanged since the date of this prospectus and any applicable prospectus supplement or that the information contained in any document incorporated by reference is accurate as of any date other than the date of the document incorporated by reference, regardless of the time of delivery of this prospectus and any applicable prospectus supplement or any sale of a security. This prospectus and any applicable prospectus supplement may only be used where it is legal to sell the securities. We urge you to read carefully this prospectus (as supplemented and amended), together with the information incorporated herein by reference as described under the heading "Incorporation of Information by Reference" before deciding whether to invest in any of the shares of common stock being offered.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the section entitled "Where You Can Find More Information."

In this prospectus, unless the context otherwise requires, the terms "Achieve," the "Company," "we," "us," and "our" refer to Achieve Life Sciences, Inc. together with its subsidiaries, taken as a whole.

#### PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus or incorporated by reference in this prospectus from our Annual Report on Form 10-K for the year ended December 31, 2022, and our other filings with the SEC listed below under the heading "Incorporation of Information by Reference." This summary may not contain all the information that you should consider before investing in securities. You should read the entire prospectus and the information incorporated by reference in this prospectus carefully, including "Risk Factors" and the financial data and related notes and other information incorporated by reference, before making an investment decision. See "Cautionary Note Regarding Forward-Looking Statements."

#### **Our Company**

We are a late-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine dependence. With more than one billion smokers globally and over 30 million smokers in the United States alone, smoking remains the leading cause of preventable disease and death, responsible for more than eight million deaths annually worldwide. Our primary focus is to address this global epidemic.

We also plan to continue expanding our focus to address other methods of nicotine addiction such ase-cigarettes/vaping. The use of e-cigarettes continues to be widespread, with most recent reports from the Centers for Disease Control and Prevention indicating nearly 11 million adult users in the United States alone in 2019. While e-cigarettes have been historically viewed as less harmful than combustible cigarettes, their long-term safety remains controversial. In a recent study that we conducted surveying approximately 500 users of nicotine vaping devices or e-cigarettes, approximately 73% of participants responded that they intend to quit vaping within the next three to 12 months. Of those who intended to quit even sooner, within the next 3 months, more than half stated they would be extremely likely to try a new prescription product to help them do so. We believe that cytisinicline, if approved, could be the first prescription drug indicated for vape and e-cigarette users who are ready to quit their nicotine addiction

#### **Corporate Information**

We were incorporated in California in October 1991 and subsequently reorganized as a Delaware corporation in March 1995. Our principal executive offices are located at 2722 29th Drive SE, Suite 100, Bothell, WA 98021 and 1040 West Georgia Street, Suite 1030, Vancouver, B.C. V6E 4H1, and our telephone number is (604) 210-2217.

## **Recent Developments**

On May 15, 2023, we entered into a contingent convertible debt agreement (the "Debt Agreement") with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company ("FCB"), in its capacity as administrative agent and collateral agent, FCB, as a lender, SVB Innovation Credit Fund VIII, L.P., as a lender ("Innovation"), and Innovation Credit Fund VIII-A, L.P., as a lender (together with FCB and Innovation, the "Lenders"), pursuant to which the Lenders provided term loans having an aggregate original principal amount of \$16.56 million (the "Convertible Term Loan"). Our obligations under the Debt Agreement are secured by substantially all of our assets, other than intellectual property.

The Debt Agreement refinanced our previous contingent convertible debt agreement (the "Prior Debt Agreement") entered into on December 22, 2021, by and among us and Silicon Valley Bank and SVB Innovation Credit Fund VIII, L.P., as lenders, pursuant to which the lenders provided us with term loans having an aggregate principal amount of \$15.0 million (the "Prior Convertible Term Loan"). Our obligations under the Prior Debt

Agreement and Prior Convertible Term Loan were satisfied in full and the Prior Debt Agreement and Prior Convertible Term Loan were terminated in connection with the entrance into the Debt Agreement and Convertible Term Loan.

The Convertible Term Loan matures on December 22, 2024; provided that (a) in the event we fail to receive written notice that the U.S. Food and Drug Administration has accepted for filing our New Drug Application ("NDA") with respect to cytisinicline for a smoking cessation indication (a "Filing Communication"), on or prior to July 31, 2024, the maturity date shall be August 1, 2024 or (b) in the event we receive a Filing Communication with respect to cytisinicline for a smoking cessation indication on or prior to August 14, 2024, but where such Filing Communication letter specifies any material deficiencies or material filing review issues with respect to such NDA, the maturity date shall be August 15, 2024; provided, further, that in the event we have submitted the NDA on or prior to June 30, 2024, the dates listed in (a) and (b) above shall be extended by one calendar month. Interest is calculated on the outstanding principal amount of the Convertible Term Loan at the aggregate of (a) a floating rate per annum equal to the greater of (i) 2.25% and (ii) the prime rate minus 1.0%, which interest shall be payable in cash monthly in arrears, and (b) 7.0% per annum, compounded monthly, which shall be payable on the earlier to occur of the maturity date and the date that the Convertible Term Loan is converted into our common stock.

The conversion feature grants the Lenders or, pursuant to an assignment, any designee thereof (each, a "Conversion Right Holder," and collectively, the "Conversion Right Holders") the right to convert part or all of the outstanding principal of the Convertible Term Loan, plus accrued and unpaid interest into shares of our common stock at a conversion price equal to \$9.34, as may be adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like occurring after May 15, 2023 (the "Conversion Price"). The conversion rights may be exercised at each Conversion Right Holder's option any time prior to repayment of the Convertible Term Loan. Additionally, the outstanding principal of the Convertible Term Loan, plus accrued and unpaid interest, will automatically be converted into shares of our common stock at the Conversion Price on the first date where (i) the closing price per share of our common stock is equal to or greater than \$24.00 for the thirty consecutive trading days prior to such date, and (ii) the "Liquidity Conditions" (as defined in the Debt Agreement) have been satisfied. Subject to the terms and conditions of the Debt Agreement, no shares of our common stock will be issued or delivered upon conversion of any amount outstanding pursuant to the Convertible Term Loan, and no outstanding debt will be convertible by any Conversion Right Holder, in each case to the extent, and only to the extent, that such issuance, delivery, conversion or convertibility would result in such Conversion Right Holder, or a "person" or "group" (within the meaning of Section 13(d)(3) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) that includes such Conversion Right Holder, beneficially owning in excess of 9.99% (the "Ownership Percentage") of the then-outstanding shares of our common stock; provided, however, that with respect to any Conversion Right Holder that is subject to Section 16(a) or (b) of the Exchange Act with respect to us by virtue of being deemed to be a "direct

In connection with our entry in the Debt Agreement, we granted to the Conversion Right Holders certain registration rights with respect to the shares of common stock issuable upon the conversion of outstanding indebtedness under the Debt Agreement pursuant to that registration rights agreement dated May 15, 2023. We are registering the shares offered hereby pursuant to such registration rights.

This prospectus is part of a registration statement that we have filed with the SEC to register 1,986,611 shares of our common stock, par value \$0.001 per share (the "Shares"), issuable to the selling stockholders upon the conversion of \$18.6 million aggregate amount of outstanding indebtedness at a conversion price equal to \$9.34 per share, including accrued and unpaid interest, pursuant to the Debt Agreement. The Shares are being registered for resale or other disposition by the selling stockholders. We will not receive any proceeds from the sale or other disposition of the Shares registered hereunder, or interests therein.

#### THE OFFERING

Common stock offered by selling stockholders 1,986,611 shares of common stock issuable to the selling stockholders upon the conversion of

\$18.6 million aggregate amount of outstanding indebtedness, including accrued and unpaid

interest, pursuant the Debt Agreement.

Use of proceeds We will not receive any proceeds from the sale of the shares of common stock covered by this

prospectus.

Risk factors See "Risk Factors" included herein, for a discussion of factors you should carefully consider

before deciding to invest in our common stock.

Nasdaq Capital Market Symbol ACHV

The selling stockholders to be identified in a prospectus supplement may offer and sell up to an aggregate of 1,986,611 shares of our common stock issuable to the selling stockholders upon the conversion of \$18.6 million aggregate amount of outstanding indebtedness at a conversion price equal to \$9.34 per share, including accrued and unpaid interest, pursuant to the Debt Agreement.

We agreed to file this prospectus pursuant to a registration rights agreement with the Lenders, dated May 15, 2023 (the "Registration Rights Agreement"). Additional information with respect to the Registration Rights Agreement is contained in this prospectus under the heading "Selling Stockholders" and in our Current Report on Form 8-K filed with the Securities and Exchange Commission on May 17, 2023.

When we refer to the selling stockholders, we are referring to the selling stockholders to be identified in a prospectus supplement and, as applicable, any donees, pledgees, transferees or other successors-in-interest selling shares received after the date of this prospectus from a selling stockholder as a gift, pledge, or other non-sale related transfer that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part.

## RISK FACTORS

An investment in our securities involves a high degree of risk. The prospectus supplement applicable to each offering of securities will contain a discussion of the risks applicable to an investment in our securities. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed under the heading "Risk Factors" in the applicable prospectus supplement, together with all of the other information contained or incorporated by reference in the prospectus supplement or appearing or incorporated by reference in this prospectus, including in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023, and other documents we file with the SEC that are deemed incorporated by reference into this prospectus, which may be amended, supplemented, or superseded from time to time by other reports we file with the SEC in the future. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains or incorporates by reference "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve a number of risks and uncertainties. We caution readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. These statements are based on current expectations of future events. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, interest rates, outcome of contingencies, financial condition, results of operations, liquidity, business strategies, cost savings, objectives of management and other statements that are not historical facts. You can find many of these statements by looking for words like "believes," "expects," "anticipates," "estimates," "may," "should," "will," "could," "plan," "intend" or similar expressions in this prospectus or in documents incorporated by reference into this prospectus. We intend that such forward-looking statements be subject to the safe harbors created thereby. Examples of these forward-looking statements include, but are not limited to:

- · our ability to raise additional capital as needed to fund our planned development and commercialization efforts and repay our existing debt;
- · progress and preliminary and future results of any clinical trials;
- anticipated regulatory filings, and FDA responses, recommendations, requirements or additional future clinical trials;
- our expectations regarding the impact of the macroeconomic and geopolitical environment, including inflation, pandemics and geopolitical conflict, and their potentially material adverse impact on our business and the execution of our preclinical studies and clinical trials;
- the performance of, and our ability to obtain sufficient supply of cytisinicline in a timely manner from, third-party suppliers and manufacturers:
- timing and plans for the expansion of our focus to address other methods of nicotine addiction;
- · timing and amount of future contractual payments, product revenue and operating expenses;
- market acceptance of our products and the estimated potential size of these markets; and
- our expectations regarding the impact of the macroeconomic and geopolitical environment, including inflation, rising interest rates, increased volatility in the debt and equity markets, instability in the global banking sector, global health crises and pandemics and geopolitical conflict, and their potentially material adverse impact on our business and the execution of our preclinical studies and clinical trials.

These forward-looking statements are based on the current beliefs and expectations of our management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results may differ materially from current expectations and projections. Factors that might cause such a difference include the risk factors identified under the caption "Risk Factors" in this prospectus, as well as those identified under Part II, Item 1A. "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 9, 2023.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus or, in the case of documents referred to or incorporated by reference, the date of those documents.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this

section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities law. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3 under the Securities Act of 1933, as amended (the "Securities Act"), with respect to the securities offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, the exhibits filed therewith or the documents incorporated by reference therein. For further information about us and the securities offered hereby, reference is made to the registration statement, the exhibits filed therewith and the documents incorporated by reference therein. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and in each instance, we refer you to the copy of such contract or other document filed as an exhibit to the registration statement.

We are subject to the informational requirements of the Exchange Act and are required to file annual, quarterly and other reports, proxy statements and other information with the SEC. The SEC maintains an Internet site (http://www.sec.gov) that contains reports, proxy and information statements, and various other information about us. You may also inspect the documents described herein at our principal executive offices, 22722 29th Drive SE, Suite 100, Bothell, Washington and 1040 West Georgia Street, Suite 1030, Vancouver, B.C. V6E 4H1, during normal business hours.

Information about us is also available at our website at https://achievelifesciences.com/. However, the information on our website is not a part of this prospectus and is not incorporated by reference into this prospectus.

#### INCORPORATION OF INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with the SEC, which means that we can disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus, and information we file later with the SEC will automatically update and supersede this information. A Current Report (or portion thereof) furnished, but not filed, on Form 8-K shall not be incorporated by reference into this prospectus. We incorporate by reference the documents listed below and any future filings we make with the SEC under Section 13(a), 13(c), 14, or 15(d) of the Exchange Act prior to the termination of any offering of securities made by this prospectus:

- our <u>Annual Report on Form 10-K</u> for the year ended December 31, 2022, as filed with the SEC on March 16, 2023 (as amended by <u>Amendment No. 1 on Form 10-K/A</u> filed with the SEC on May 16, 2023);
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, as filed with the SEC on May 9, 2023;
- our Current Reports on Form 8-K filed with the SEC on March 23, 2023, March 30, 2023 (excluding any information furnished in such report under Item 7.01), May 17, 2023, May 23, 2023, May 25, 2023 and June 9, 2023;
- our Definitive Proxy Statement on Schedule 14A filed with the SEC on April 28, 2023 (but only with respect to information required by Part III of our Annual Report on Form 10-K for the year ended December 31, 2022);
- the description of our common stock contained in our registration statement on Form8-A filed with the SEC on September 27, 1995 (paper filing) under Section 12 of the Exchange Act, including any amendment or report filed for the purpose of updating such description; and
- filings we make with the SEC pursuant to the Exchange Act after the date of the initial registration statement, of which this prospectus is a part, and prior to the effectiveness of the registration statement.

We will furnish without charge to you, on written or oral request, a copy of any or all of such documents that has been incorporated herein by reference (other than exhibits to such documents unless such exhibits are specifically incorporated by reference into the documents that this prospectus incorporates). You may request a copy of these filings (other than an exhibit to a filing unless that exhibit is specifically incorporated by reference into that filing) at no cost by writing, telephoning or e-mailing us at the following address, telephone number or e-mail address:

Achieve Life Sciences, Inc. 2722 29th Drive SE, Suite 100 Bothell, WA 98021 Tel: (604) 210-2217 Attn: Sandra Thomson

Copies of these filings are also available through the "Investors" section of our website at www.achievelifesciences.com. See the section of this prospectus entitled "Where You Can Find More Information" for information concerning how to obtain copies of materials that we file with the SEC.

Any statement contained in this prospectus, or in a document, all or a portion of which is incorporated by reference, shall be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus, any prospectus supplement or any document incorporated by reference modifies or supersedes such statement. Any such statement so modified or superseded shall not, except as so modified or superseded, constitute a part of this prospectus.

## USE OF PROCEEDS

The proceeds from the sale of the Shares offered pursuant to this prospectus are solely for the accounts of the selling stockholders. Accordingly, we will not receive any of the proceeds from the sale of the Shares offered by this prospectus. See "Selling Stockholders" and "Plan of Distribution" below.

The selling stockholders will pay any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the securities. We will bear the costs, fees and expenses incurred in effecting the registration of the securities covered by this prospectus, including all registration and filing fees, Nasdaq listing fees and fees and expenses of our counsel and our independent registered public accounting firm.

#### PLAN OF DISTRIBUTION

Each selling stockholder of the Shares and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their Shares on the NASDAQ Capital Market or any other stock exchange, market or trading facility on which the Shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling Shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the Shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling stockholders to sell a specified number of such Shares at a stipulated price per share;
- · through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Prior to such time that the selling stockholders offer and sell Shares, we or such selling stockholders will provide a supplement to this prospectus that contains specific information about the selling stockholders. The supplement may also add, update or change information contained in this prospectus with respect to any offering of the Shares. You should carefully read this prospectus and the applicable prospectus supplement before you invest in our common stock.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of Shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the Shares or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the Shares in the course of hedging the positions they assume. The selling stockholders may also sell shares of the common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of Shares offered by this prospectus, which Shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the Shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such

event, any commissions received by such broker-dealers or agents and any profit on the resale of the Shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock.

We are required to pay certain fees and expenses incurred by us incident to the registration of the Shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. There is no underwriter or coordinating broker acting in connection with the proposed sale of the Shares by the selling stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the Shares may be resold by the selling stockholders without registration and without the requirement to be in compliance with Rule 144(c)(1) and otherwise without restriction or limitation pursuant to Rule 144 or (ii) all of the Shares have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The Shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the Shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the Shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act or any similar rule).

## SELLING STOCKHOLDERS

This prospectus relates to the possible resale by the selling stockholders to be identified in a prospectus supplement of up to 1,986,611 shares issuable to the selling stockholders upon the conversion of \$18.6 million aggregate amount of outstanding indebtedness, including accrued and unpaid interest, at a conversion price equal to \$9.34 per share, originally acquired by FCB, SVB Innovation Credit Fund VIII, L.P., and Innovation Credit Fund VIII-A, L.P., as lenders pursuant to that certain Convertible Debt Agreement. Pursuant to the Registration Rights Agreement, we have agreed to file a registration statement with the SEC covering the resale of shares of our capital stock, and this registration statement has been filed pursuant to the Registration Rights Agreement.

Information about the selling stockholders, where applicable, including their identities, the amount of Shares owned by each selling stockholder prior to the offering, the number of Shares to be offered by each selling stockholder and the amount of Shares to be owned by each selling stockholder after completion of the offering, will be set forth in an applicable prospectus supplement, documents incorporated by reference or in a free writing prospectus we file with the SEC. The applicable prospectus supplement will also disclose whether any of the selling stockholders has held any position or office with, has been employed by or otherwise has had a material relationship with us during the three years prior to the date of the prospectus supplement.

The selling stockholders may not sell any Shares pursuant to this prospectus until we have identified such selling stockholders and the Shares being offered for resale by such selling stockholders in a subsequent prospectus supplement. However, the selling stockholders may sell or transfer all or a portion of their Shares pursuant to any available exemption from the registration requirements of the Securities Act.

The number of shares of common stock that will actually be issued to the selling stockholders may be more or less than the number of Shares being offered by this prospectus. In addition, the Shares may be sold pursuant to this prospectus or in privately negotiated transactions. See "Plan of Distribution." Because the selling stockholders may sell all, some or none of their Shares in this offering and because there are currently no agreements, arrangements or undertakings with respect to the sale of any of the Shares, we cannot estimate the number of Shares the selling stockholders will sell under this prospectus. The fourth column of the table assumes the sale of all of the Shares offered by the selling stockholders pursuant to this prospectus.

## LEGAL MATTERS

Fenwick & West LLP, Seattle, Washington, will issue an opinion about certain legal matters with respect to the securities. Any underwriters or agents will be advised about legal matters relating to any offering by their own counsel.

## **EXPERTS**

The financial statements incorporated in this prospectus by reference to the Annual Report on Form10-K for the year ended December 31, 2022 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 14. Other Expenses of Issuance and Distribution

The following table sets forth estimated expenses in connection with the issuance and distribution of the securities being registered:

	Amount
	to be
<u>Item</u>	<u>paid</u>
SEC registration fee	\$ 1,307
Printing and engraving*	*
Legal fees and expenses*	*
Accounting fees and expenses*	*
Transfer agent and registrar fees and expenses*	*
Miscellaneous expenses*	*
Total*	\$ *

\* Estimated expenses cannot be known at this time

## Item 15. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers under certain circumstances and subject to certain limitations. The terms of Section 145 of the Delaware General Corporation Law are sufficiently broad to permit indemnification under certain circumstances for liabilities, including reimbursement of expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act.

As permitted by the Delaware General Corporation Law, the Registrant's restated certificate of incorporation contains provisions that eliminate the personal liability of its directors for monetary damages for any breach of fiduciary duties as a director, except liability for the following:

- any breach of the director's duty of loyalty to the Registrant or its stockholders;
- · acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- under Section 174 of the Delaware General Corporation Law (regarding unlawful dividends or stock purchases); or
- · any transaction from which the director derived an improper personal benefit.

As permitted by the Delaware General Corporation Law, the Registrant's restated bylaws provide that:

- the Registrant is required to indemnify its directors and executive officers to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;
- the Registrant may indemnify its other employees and agents as set forth in the Delaware General Corporation Law;
- the Registrant is required to advance expenses, as incurred, to its directors and executive officers in connection with a legal proceeding to the
  fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; and
- the rights conferred in the restated bylaws are not exclusive.

The Registrant has entered, and intends to continue to enter, into indemnification agreements with each of its directors and executive officers to provide these directors and executive officers additional contractual

assurances regarding the scope of the indemnification set forth in the Registrant's restated certificate of incorporation and restated bylaws and to provide additional procedural protections. At present, there is no pending litigation or proceeding involving a director or executive officer of the Registrant for which indemnification is sought. The indemnification provisions in the Registrant's restated certificate of incorporation, restated bylaws and the indemnification agreements entered into or to be entered into between the Registrant and each of its directors and executive officers may be sufficiently broad to permit indemnification of the Registrant's directors and executive officers for liabilities arising under the Securities Act.

The Registrant currently carries liability insurance for its directors and officers.

#### Item 16. Exhibits

The exhibits listed below are filed (except where otherwise indicated) as part of this Registration Statement.

Exhibit			Incorporated by Reference			
Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Herewith
4.1	Form of Registrant's Common Stock certificate	10-Q	000-21243	4.1	11/10/2008	
4.2	Form of Registration Rights Agreement	8-K	033-80623	10.2	5/17/2023	
5.1	Opinion of Fenwick & West LLP					X
23.1	Consent of Fenwick & West LLP (contained in Exhibit 5.1)					X
23.2	Consent of PricewaterhouseCoopers LLP, Independent Registered Public					
	Accounting Firm					X
24.1	Power of Attorney (included on the signature page hereto)					X
107	Filing Fee Table					X

<sup>\*</sup> To be filed by amendment or as an exhibit to a report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and incorporated herein by reference.

#### Item 17. Undertakings

- (a) The undersigned Registrant hereby undertakes:
  - (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
    - $(i) \ to \ include \ any \ prospectus \ required \ by \ Section \ 10(a)(3) \ of \ the \ Securities \ Act \ of \ 1933;$
    - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of

<sup>\*\*</sup> To be filed in accordance with the requirements of Section 305(b)(2) of the Trust Indenture Act of 1939 and Rule5b-3 thereunder.

prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that subparagraphs (i), (ii), and (iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Securities and Exchange Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
  - (i) Each prospectus filed by the Registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
  - (ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.
- (5) That, for the purpose of determining liability of the Registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned Registrant undertakes that in a primary offering of securities of the undersigned Registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
  - (i) any preliminary prospectus or prospectus of the undersigned Registrant relating to the offering required to be filed pursuant to Rule 424;
  - (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned Registrant or used or referred to by the undersigned Registrant;

- (iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned Registrant or its securities provided by or on behalf of the undersigned Registrant; and
- (iv) any other communication that is an offer in the offering made by the undersigned Registrant to the purchaser.
- (b) The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

## **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Seattle, Washington, on June 14, 2023.

## ACHIEVE LIFE SCIENCES, INC.

By: /s/ John Bencich
John Bencich
Chief Executive Officer

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints John Bencich and Richard Stewart, and each of them, as his true and lawful attorneys-in-fact, proxies and agents, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments or any abbreviated registration statement and any amendments thereto filed pursuant to Rule 462(b) increasing the number of securities for which registration is sought), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact, proxies and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, proxies and agents, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
/s/ John Bencich John Bencich	Chief Executive Officer and Director (Principal Executive Officer and Principal Financial Officer)	June 14, 2023
/s/ Jerry Wan Jerry Wan	Senior Director of Accounting Operations (Principal Accounting Officer)	June 14, 2023
/s/ Richard Stewart Richard Stewart	Executive Chairman and Director	June 14, 2023
/s/ Stuart Duty Stuart Duty	Director	June 14, 2023
/s/ Vaughn Himes Vaughn Himes	Director	June 14, 2023
/s/ Cindy Jacobs Cindy Jacobs	Director	June 14, 2023
Thomas B. King	Director	June 14, 2023
/s/ Bridget Martell Bridget Martell	Director	June 14, 2023
/s/ Thomas Sellig Thomas Sellig	Director	June 14, 2023



401 Union Street 5th Floor Seattle, WA 98101

206.389.4510 Fenwick.com

June 14, 2023

Achieve Life Sciences, Inc. 22722 29th Drive SE, Suite 100 Bothell, WA 98021

#### Ladies and Gentlemen:

At your request, we have examined the Registration Statement on Form S-3 filed by Achieve Life Sciences, Inc., a Delaware corporation (the "Company"), with the Securities and Exchange Commission (the "Commission") on June 14, 2023 (the "Registration Statement"), in connection with the registration under the Securities Act of 1933, as amended (the "Securities Act"), of an aggregate of 1,986,611 shares (the "Shares") of the Company's common stock, \$0.001 par value per share (the "Common Stock"), issuable by the Company to the selling stockholders (collectively, the "Selling Stockholders") upon the conversion of outstanding indebtedness, including accrued and unpaid interest (the "Convertible Term Loan"), pursuant to that certain Convertible Debt Agreement (the "Debt Agreement"), dated May 15, 2023, by and among the Company and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company ("FCB") in its capacity as administrative agent and collateral agent, FCB, as a lender, SVB Innovation Credit Fund VIII, L.P., as a lender, and Innovation Credit Fund VIII, L.P., as a lender, and Innovation Credit Fund VIII-A, L.P., as a lender. The Shares may be sold from time to time by the Selling Stockholders as set forth in the Registration Statement and the prospectus contained within the Registration Statement (the "Prospectus").

In connection with our opinion expressed below we have examined originals or copies of the Company's Third Amended and Restated Certificate of Incorporation (the "Certificate"), the Company's Sixth Amended and Restated Bylaws, as amended (the "Bylaws"), certain corporate proceedings of the Company's board of directors and stockholders relating to the Registration Statement, the Certificate and Bylaws, and such other agreements, documents, certificates and statements of the Company, its transfer agent and public or government officials, as we have deemed advisable, and have examined such questions of law as we have considered necessary. We have assumed the authenticity of all documents submitted to us as originals, the genuineness of all signatures on documents submitted to us, the conformity to originals of all documents submitted to us as copies, and the absence of any undisclosed termination, waiver or amendment to any document reviewed by us. In giving our opinion, we have also relied upon a good standing certificate issued by the Delaware Secretary of State and representations made to us by the Company, including representations that the Company has available a sufficient number of authorized shares of Common Stock that are not currently outstanding or reserved for issuance under other outstanding securities or equity plans of the Company, to enable the Company to issue and deliver all of the Shares issuable upon exercise of the Convertible Term Loan as of the date of this opinion.

We render this opinion only with respect to, and express no opinion herein concerning the application or effect of the laws of any jurisdiction other than, the existing laws of the Delaware General Corporation Law.

Based upon the foregoing, we are of the opinion that, the Shares that may be sold by the Selling Stockholders pursuant to the Registration Statement will, when delivered in the manner and for the consideration stated in the Registration Statement and the Prospectus, and when issued in accordance with the terms and conditions of the Debt Agreement, be validly issued, fully paid and nonassessable.

We consent to the use of this opinion as an exhibit to the Registration Statement and further consent to all references to us, if any, in the Registration Statement, the Prospectus constituting a part thereof and any amendments thereto. We do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder. This opinion is intended solely for use in connection with sale of the Shares to be sold by the Selling Stockholders pursuant to the Registration Statement and is not to be relied upon for any other purpose. In providing this letter, we are opining only as to the specific legal issues expressly set forth above, and no opinion shall be inferred as to any other matter or matters. This opinion is rendered on, and speaks only as of, the date of this letter first written above, and does not address any potential change in facts of law that may occur after the date of this opinion letter. We assume no obligation to advise you of any fact, circumstance, event or change in the law or the facts that may hereafter be brought to our attention, whether or not such occurrence would affect or modify any of the opinions expressed herein.

Very truly yours,

/s/ Fenwick & West LLP FENWICK & WEST LLP  $Consent\ of\ Independent\ Registered\ Public\ Accounting\ Firm$ 

We hereby consent to the incorporation by reference in this registration statement on FormS-3 of Achieve Life Sciences, Inc. of our report dated March 16, 2023 relating to the financial statements of Achieve Life Sciences, Inc., which appears in Achieve Life Sciences, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2022. We also consent to the reference to us under the heading "Experts" in such registration statement.

/s/ PricewaterhouseCoopers LLP

## **Chartered Professional Accountants**

Vancouver, Canada

June 14, 2023

## Calculation Of Filing Fee Tables

Form S-3 (Form Type)

Achieve Life Sciences, Inc. (Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

Security Type	Security Class Title	Fee Calculation Rule	Amount Registered(1)	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Equity	Common stock, par value \$0.001 per share	Rule 457(c)	1,986,611(2)	\$5.97(3)	\$11,860,068	\$0.0001102	\$1,307
Total Offering Amounts						\$1,307	
Total Fees Previously Paid				•		_	
Total Fee Offsets						_	
Net Fee Due						\$1,307	

- (1) Represents the shares of Common Stock, par value \$0.001 per share (the "Common Stock") of Achieve Life Sciences, Inc. (the "Registrant") that will be offered for resale by the selling stockholders pursuant to the prospectus to which this exhibit is attached. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), the shares being registered hereunder include such indeterminate number of additional shares of Common Stock as may be issuable as a result of stock splits, stock dividends or similar transactions with respect to the shares being registered hereunder.
- (2) Consists of an aggregate of 1,986,611 shares of the Registrant's Common Stock issuable to the selling stockholders upon the conversion of \$18.6 million aggregate principal amount of outstanding indebtedness at a conversion price equal to \$9.34 per share, including accrued and unpaid interest.
- (3) Estimated in accordance with Rule 457(c) under the Securities Act solely for the purpose of calculating the registration fee on the basis of \$5.97, the average of the high and low prices of the Common Stock as reported on The Nasdaq Capital Market on June 13, 2023.