
**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)

Richard Stewart
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:

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Alan Smith, Esq.
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401 Union Street, 5th Floor
Seattle, WA 98101
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From time to time after this registration statement becomes effective.
(Approximate date of commencement of proposed sale to the public)

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 7(a)(2)(B) of Securities Act.

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 NOVEMBER 7, 2024

PROSPECTUS

3,488,727 Shares of Common Stock

This prospectus relates to the registration for potential offer and sale from time to time of up to an aggregate of 3,488,727 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 (i) up to 1,428,571 Shares issuable to the selling stockholders upon the conversion of the first tranche of \$10.0 million aggregate principal amount of outstanding indebtedness at a conversion price equal to \$7.00 per share, (ii) up to 1,030,078 Shares issuable to the selling stockholders upon the conversion of the second tranche of \$5.0 million aggregate principal amount of outstanding indebtedness at an assumed conversion price equal to \$4.854 per share, and (iii) up to 1,030,078 Shares issuable to the selling stockholders upon the conversion of the third tranche of \$5.0 million aggregate principal amount of outstanding indebtedness at an assumed conversion price equal to \$4.854 per share, in each case 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. 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 November 6, 2024 the last reported sales price for our common stock was \$5.12 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 11 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 November 7, 2024

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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, 2023, 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

Our focus is to address the global nicotine addiction epidemic in combustible cigarette and e-cigarette usage through the development and commercialization of cytisinicline. There are an estimated 29 million adults in the United States alone who smoke combustible cigarettes. Tobacco use is currently the leading cause of preventable death and is responsible for more than 8.0 million deaths worldwide and nearly half a million deaths in the United States annually. More than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease are attributable to smoking and exposure to secondhand smoke.

In addition, there are approximately 11 million adults in the United States who use e-cigarettes, also known as vaping. While nicotine e-cigarettes are thought to be less harmful than combustible cigarettes, they remain addictive and can deliver harmful chemicals which can cause lung injury or cardiovascular disease. In 2024, 1.6 million high school and middle school students reported using e-cigarettes. Research shows adolescents who have used e-cigarettes are seven times more likely to become smokers one year later compared to those who have never vaped. Recently, the U.S. Food and Drug Administration, or FDA, granted Breakthrough Therapy designation for cytisinicline for nicotine e-cigarette, or vaping, cessation. Breakthrough Therapy designation allows expedited development of drugs that are intended to treat serious conditions, when preliminary clinical evidence indicates that the drug demonstrates substantial improvement over available therapies. Currently, there are no FDA approved therapies indicated specifically as an aid to nicotine e-cigarette cessation.

Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in treating nicotine addiction for smoking and e-cigarette cessation by interacting with nicotine receptors in the brain, reducing the severity of withdrawal symptoms, and reducing the reward and satisfaction associated with nicotine products. Cytisinicline is an investigational product candidate being developed for treatment of nicotine addiction and has not been approved by the FDA for any indication in the United States.

We believe cytisinicline represents a unique opportunity to significantly impact global health by addressing the considerable unmet need among millions of smokers and e-cigarettes users. If approved by the FDA, it may become one of the first new prescription medicines in nearly two decades aimed at aiding individuals in overcoming nicotine dependence. We believe cytisinicline is differentiated from existing smoking cessation treatments given its combination of robust efficacy, minimal frequency of side effects and optional shorter course of therapy.

Our management team has significant experience in growing emerging companies focused on the development of under-utilized pharmaceutical compounds to meet unmet medical needs. We intend to use this experience to develop and ultimately commercialize cytisinicline either directly or via strategic collaborations.

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 July 25, 2024, 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 (in such capacity, the “Agent”), and FCB, as a lender (the “Lender”), pursuant to which the Lender provided term loans having an aggregate original principal amount of \$10.0 million, with additional term loans of up to \$10.0 million available upon the occurrence of certain events as provided for in the Debt Agreement and further described below (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 May 15, 2023, by and among us, FCB, in its capacity as administrative agent and collateral agent, and FCB, SVB Innovation Credit Fund VIII, L.P., and Innovation Credit Fund VIII-A, L.P., as lenders, pursuant to which such lenders provided us with terms loans having an aggregate principal amount of \$16.6 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 1, 2027, which maturity date may be extended to June 1, 2028 upon the occurrence of certain events as provided for in the Debt Agreement. The first tranche of the Convertible Term Loan, which was advanced on July 25, 2024, has an aggregate original principal amount of \$10.0 million. The Lender will further make available to us, upon our request: (a) on or prior to October 31, 2025, a second tranche of the Convertible Term Loan having an aggregate principal amount of \$5.0 million in the event that we receive written notice that the FDA has accepted for filing our New Drug Application with respect to cytisnicline for a smoking cessation indication, and (b) on or prior to December 31, 2025, a third tranche of the Convertible Term Loan having an aggregate principal amount of \$5.0 million, subject to the Lender’s sole discretion. Interest is calculated on the outstanding principal amount of the Convertible Term Loan at a floating rate per annum equal to the greater of (i) 7.0% and (ii) the prime rate minus 1.0%, which interest shall be payable in cash monthly in arrears and shall be payable on the earlier to occur of (x) the first day of the first month following any extension of credit by the Lender for our credit, (y) the date of any prepayment pursuant to the Debt Agreement, or (z) the maturity date. The Convertible Term Loan will be “interest-only” until December 31, 2025, subject to extension as provided for in the Debt Agreement.

The conversion feature grants the Lender 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 aggregate original principal amount of the Convertible Term Loan, plus accrued and unpaid interest, into shares of our common stock (an “Initial Voluntary Conversion”) at a conversion price equal to \$7.00, as may be adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like (the “Initial Conversion Price”), for a maximum of 1,428,571 shares of common stock (the “Initial Conversion Shares”). The Conversion Rights Holders have the further right to convert part or all of the outstanding principal amount of the second and third tranches of the Convertible Term Loan, plus accrued and unpaid interest, into shares of our common stock (a “Subsequent Voluntary Conversion,” and together with an Initial Voluntary Conversion, a “Voluntary Conversion”) at a conversion price equal to the greater of (i) \$4.854, as may be adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like, and (ii) the lower of (a) 150% of the average of the closing sale price of our common stock during the 10 trading days preceding the effective date of such tranche and (b) 150% of the closing sale price of our common stock on the trading day immediately preceding the effective date of such tranche (the “Subsequent Conversion Price,” and together with the Initial Conversion Price, the “Conversion Price”), for a maximum of 2,060,156 shares of common stock (the “Subsequent Conversion Shares,” and together with the Initial Conversion Shares, the “Conversion Shares”).

The conversion rights may be exercised at each Conversion Right Holder’s option any time prior to repayment of the Convertible Term Loan; provided, however, that a Voluntary Conversion will not be permitted without the agreement of the relevant Conversion Right Holder and us if the “Conversion Percentage Amount” (as defined in the Debt Agreement) exceeds 50%. Additionally, the outstanding principal of the Convertible Term Loan, plus

accrued and unpaid interest, will automatically be converted into Conversion Shares 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 (a) in the case of the outstanding aggregate original principal amount of the Convertible Term Loan, \$24.00 or, (b) in the case of the outstanding principal amount of the second and third tranches of the Convertible Term Loan, three times the applicable Subsequent Conversion Price, in each case, 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 Conversion Shares 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 “director” or “officer” of our company within the meaning of Section 16 of the Exchange Act, the applicable Ownership Percentage shall be 19.99%; and provided, further, that with respect to any Conversion Right Holder that is subject to the U.S. Bank Holding Company Act of 1956, as amended, the applicable Ownership Percentage shall be 4.99%. Any Conversion Shares will be issued in a private placement exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”).

The Convertible Term Loan may be repaid at our election and upon notice to the Agent by paying the Lender an amount equal to (i) a prepayment fee equal to (a) 3.0% of the aggregate outstanding principal balance if such prepayment occurs on or prior to the first anniversary of the Convertible Term Loan, (b) 2.0% of the aggregate outstanding principal balance if such prepayment occurs after the first anniversary, but on or prior to the second anniversary, of the Convertible Term Loan or (c) 1.0% of the aggregate outstanding principal balance if such prepayment occurs after the second anniversary of the Convertible Term Loan and before the maturity date; (ii) 4.0% of the original aggregate principal amount of the Convertible Term Loan and (iii) all other sums due and payable under the Convertible Term Loan.

The Debt Agreement contains customary affirmative and restrictive covenants, including covenants regarding the incurrence of additional indebtedness or liens, investments, transactions with affiliates, delivery of financial statements, payment of taxes, maintenance of insurance, dispositions of property, mergers or acquisitions, among other customary covenants. We are also restricted from paying dividends or making other distributions or payments on its capital stock, subject to limited exceptions. The Debt Agreement also includes customary representations and warranties, events of default and termination provisions. The Lender may not engage in any short sales of, or other hedging transactions in, Achieve’s common stock while any amounts are outstanding under the Debt Agreement.

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 July 25, 2024. 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 up to an aggregate of 3,488,727 shares of our common stock, par value \$0.001 per share (the “Shares”), issuable to the selling stockholders upon the conversion of the Convertible Term Loan at the applicable Conversion Price. 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	Up to 3,488,727 shares of common stock issuable to the selling stockholders upon the conversion of up to \$20.0 million aggregate amount of outstanding indebtedness, including accrued and unpaid interest, pursuant to 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 3,488,727 shares of our common stock issuable to the selling stockholders upon the conversion of up to \$20.0 million aggregate amount of outstanding indebtedness at the applicable Conversion Price, including accrued and unpaid interest, pursuant to the Debt Agreement.

We agreed to file this prospectus pursuant to a registration rights agreement with the Lender, dated July 25, 2024 (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 July 29, 2024.

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 September 30, 2024, 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:

- progress and preliminary and future results of any clinical trials;
- anticipated regulatory filings and FDA responses, recommendations, requirements or additional future clinical trials;
- our ability to raise additional capital as needed to fund our planned development and commercialization efforts and repay our existing debt;
- the potential benefits and differentiated profile, FDA approval, commercialization and commercial market for cytisinicline;
- 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, increased volatility in interest rates and the debt and equity markets, instability in the global banking system, 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 trial.

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 September 30, 2024, filed with the SEC on November 7, 2024.

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, 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 [Annual Report on Form 10-K](#) for the year ended December 31, 2023, as filed with the SEC on March 28, 2024;
- our Quarterly Reports on Form 10-Q for the quarter ended [March 31, 2024](#), as filed with the SEC on May 9, 2024, the quarter ended June 30, 2024, as filed with the SEC on [August 13, 2024](#) and the quarter ended September 30, 2024, as filed with the SEC on [November 7, 2024](#);
- our Current Reports on Form 8-K filed with the SEC on [February 29, 2024](#), [June 6, 2024](#), [July 29, 2024](#), [August 26, 2024](#) and [September 27, 2024](#);
- our Definitive Proxy Statement on Schedule 14A filed with the SEC on [April 26, 2024](#) (but only with respect to information required by Part III of our Annual Report on Form 10-K for the year ended December 31, 2023);
- the description of our common stock contained in our registration statement on Form 8-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 3,488,727 shares issuable to the selling stockholders upon the conversion of up to \$20.0 million aggregate amount of outstanding indebtedness, including accrued and unpaid interest, at the applicable Conversion Price, originally acquired by FCB, as lender, pursuant to the 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 Form 10-K for the year ended December 31, 2023 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:

Item	Amount to be paid
SEC registration fee	\$ 2,499.71
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 Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
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	7/29/2024	
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

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 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 or made in a document 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 Bothell, Washington, on November 7, 2024.

ACHIEVE LIFE SCIENCES, INC.

By: /s/ Richard Stewart
Richard Stewart
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Richard Stewart and Thomas B. King, 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.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Richard Stewart</u> Richard Stewart	Chief Executive Officer and Director (Principal Executive Officer and Principal Financial Officer)	November 7, 2024
<u>/s/ Jerry Wan</u> Jerry Wan	Senior Director of Accounting Operations (Principal Accounting Officer)	November 7, 2024
<u>/s/ Thomas B. King</u> Thomas B. King	Executive Chairman and Director	November 7, 2024
<u>/s/ Stuart Duty</u> Stuart Duty	Director	November 7, 2024
<u>/s/ Vaughn Himes</u> Vaughn Himes	Director	November 7, 2024
<u>/s/ Cindy Jacobs</u> Cindy Jacobs	Director	November 7, 2024
<u>/s/ Bridget Martell</u> Bridget Martell	Director	November 7, 2024
<u>/s/ Thomas Sellig</u> Thomas Sellig	Director	November 7, 2024



401 Union Street
5th Floor
Seattle, WA 98101

206.389.4510
Fenwick.com

November 7, 2024

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

Ladies and Gentlemen:

As counsel to Achieve Life Sciences, Inc., a Delaware corporation (the "**Company**"), we have examined the Registration Statement on Form S-3 filed by the Company with the Securities and Exchange Commission (the "**Commission**") on November 7, 2024 (the "**Registration Statement**"), including a related prospectus included in the Registration Statement (the "**Prospectus**"), in connection with the registration under the Securities Act of 1933, as amended (the "**Securities Act**"), of an aggregate of 3,488,727 shares (the "**Shares**") of the Company's common stock, \$0.001 par value per share, issuable by the Company to the selling stockholders (collectively, the "**Selling Stockholders**") upon the conversion of indebtedness, including accrued and unpaid interest, pursuant to that certain Convertible Debt Agreement (the "**Debt Agreement**"), dated July 25, 2024, 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, and FCB, 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. This letter is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or related Prospectus, other than as expressly stated herein with respect to the sale of the Shares by the Selling Stockholders.

As to matters of fact relevant to the opinions rendered herein, we have examined such documents, certificates and other instruments which we have deemed necessary or advisable, including a certificate addressed to us and dated the date hereof executed by the Company. We have not undertaken any independent investigation to verify the accuracy of any such information, representations or warranties or to determine the existence or absence of any fact, and no inference as to our knowledge of the existence or absence of any fact should be drawn from our representation of the Company or the rendering of the opinions set forth below. We have not considered parol evidence in connection with any of the agreements or instruments reviewed by us in connection with this letter.

In our examination of documents for purposes of this letter, we have assumed, and express no opinion as to, the genuineness and authenticity of all signatures on original documents, the authenticity and completeness of all documents submitted to us as originals, that each document is what it purports to be, the conformity to originals of all documents submitted to us as copies or facsimile copies, the absence of any termination, modification or waiver of or amendment to any document reviewed by us (other than as has been disclosed to us), the legal competence or capacity of all persons or entities (other than the Company) executing the same and (other than the Company) the due authorization, execution and delivery of all documents by each party thereto. We have also assumed the conformity of the documents filed with the Commission via the Electronic Data Gathering, Analysis and Retrieval System ("**EDGAR**"), except for required EDGAR formatting changes, to physical copies submitted for our examination.

The opinions in this letter are limited to the existing General Corporation Law of the State of Delaware now in effect. We express no opinion with respect to any other laws.

In connection with our opinion expressed below, we have assumed that, (i) the Registration Statement and any amendments (including any necessary post-effective amendments) will have been declared effective under the Securities Act, (ii) the Registration Statement will apply to the sale of the Shares and will not have been modified or rescinded and (iii) the Company's Third Amended and Restated Certificate of Incorporation, a form of which has been filed as an exhibit to the Registration Statement is filed with the Secretary of State of the State of Delaware before issuance of the Shares.

Based upon the foregoing, and subject to the qualifications and exceptions contained herein, 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 and any amendments thereto. In giving this consent we do not thereby admit that we come 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.

[Concluding Paragraph Follows on Next Page]

This opinion is intended solely for use in connection with sale of the Shares 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, is based solely on our understanding of facts in existence as of such date after the aforementioned examination and does not address any potential changes in facts, circumstance or 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 Form S-3 of Achieve Life Sciences, Inc. of our report dated March 28, 2024 relating to the consolidated 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, 2023.

We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/PricewaterhouseCoopers LLP

Chartered Professional Accountants
Vancouver, Canada

November 7, 2024

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(2)	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Equity	Common stock, par value \$0.001 per share	Rule 457(c)	3,488,727(3)	\$4.68	\$16,327,242.36	0.00015310	\$2,499.71
Total Offering Amounts							\$2,499.71
Total Fees Previously Paid							—
Total Fee Offsets							—
Net Fee Due							\$2,499.71

- (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) Estimated in accordance with Rule 457(c) under the Securities Act solely for the purpose of calculating the registration fee on the basis of \$4.68, the average of the high and low prices of the Common Stock as reported on The Nasdaq Capital Market on November 1, 2024.
- (3) Consists of an aggregate of (i) up to 1,428,571 shares of the Registrant’s Common Stock issuable to the selling stockholders upon the conversion of the first tranche of \$10.0 million aggregate principal amount of outstanding indebtedness at a conversion price equal to \$7.00 per share, (ii) up to 1,030,078 shares of the Registrant’s Common Stock issuable to the selling stockholders upon the conversion of the second tranche of \$5.0 million aggregate principal amount of outstanding indebtedness at an assumed conversion price equal to \$4.854 per share and (iii) up to 1,030,078 shares of the Registrant’s Common Stock issuable to the selling stockholders upon the conversion of the third tranche of \$5.0 million aggregate principal amount of outstanding indebtedness at an assumed conversion price equal to \$4.854 per share, in each case including accrued and unpaid interest.