
**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

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 APRIL 26, 2024

PROSPECTUS



13,086,151 Shares of Common Stock

This prospectus relates to the registration for potential offer and sale from time to time of up to 13,086,151 shares of our common stock, par value \$0.001 per share (the “Selling Stockholder Shares”), by the selling stockholders identified in the “Selling Stockholders” section of this prospectus, issuable to certain of the selling stockholders upon exercise of certain outstanding common stock purchase warrants or pre-funded warrants acquired upon the exercise of the outstanding common stock purchase warrants held by such selling stockholders (collectively, the “Warrants”). For more information regarding the Selling Stockholder Shares, see “Selling Stockholders” herein.

The selling stockholders may sell the Selling Stockholder 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 Selling Stockholder 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 Selling Stockholder 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 Selling Stockholder Shares by the selling stockholders. This prospectus also relates to the issuance by us of the shares of common stock issuable upon the exercise of Warrants. We will receive proceeds from any exercise of the Warrants for cash. We will pay the expenses incurred in registering the Selling Stockholder Shares, including legal and accounting fees.

Our common stock is traded on The Nasdaq Capital Market under the symbol “ACHV.” On April 24, 2024 the last reported sales price for our common stock was \$4.54 per share. None of the other securities we may offer are currently traded on any securities exchange.

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 10 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 , 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 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. We will not receive any proceeds from the sale by such selling stockholders of the securities offered by them described in this prospectus. This prospectus also relates to the issuance by us of the shares of common stock issuable upon the exercise of Warrants. We will receive proceeds from any exercise of the Warrants for cash.

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

We are a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine addiction. With more than one billion people who use tobacco globally and over 28 million adults who smoke 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 believe that 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 U.S. Food and Drug Administration ("FDA") it stands to become the first new prescription medicine in nearly two decades aimed at aiding individuals in overcoming nicotine dependence. We believe cytisinicline is differentiated from existing smoking cessation treatments given it has demonstrated in two randomized placebo controlled Phase 3 studies a combination of robust efficacy, minimal frequency of side effects and optional shorter course of therapy.

We plan to continue expanding our focus to address other methods of nicotine addiction such as e-cigarettes/vaping. The use of e-cigarettes continues to be widespread, with most recent reports from the Centers for Disease Control and Prevention indicating more than 11 million adult users in the United States alone in 2021. While e-cigarettes have been historically viewed as less harmful than combustible cigarettes, their long-term safety remains controversial. 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.

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 February 28, 2024, we entered into a securities purchase agreement (the "Purchase Agreement") with certain purchasers, pursuant to which we sold 13,086,151 shares of common stock at a price of \$4.585 per share in a registered direct offering. The offering of the shares was made pursuant to our shelf registration statement on Form S-3 (Reg. No. 333-261811), including the prospectus dated January 5, 2022 contained therein, and the prospectus supplement dated February 29, 2024.

In a concurrent private placement, we issued unregistered warrants (the "Cash Warrants") to purchase up to 13,086,151 shares of common stock at an exercise price of \$4.906 per share (provided, however, that the purchaser may elect to exercise the warrants for pre-funded warrants (the "Pre-Funded Warrants" and, together with the Cash Warrants, the "Warrants") in lieu of shares of common stock at an exercise price of \$4.906, minus \$0.001, the exercise price of each Pre-Funded Warrant). The Cash Warrants are immediately exercisable for shares of common stock or Pre-Funded

Warrants in lieu thereof, and will expire on the earlier of (i) three and one-half years following the date of issuance and (ii) 30 days following our public disclosure of the acceptance of a New Drug Application for cytisinicline by the FDA in a Day 74 Letter or equivalent correspondence.

The registered direct offering raised total gross proceeds of approximately \$60.0 million, and after deducting approximately \$3.9 million in placement agent fees and offering expenses, we received net proceeds of approximately \$56.1 million. Pursuant to the Purchase Agreement, we granted to the participating accredited investors certain registration rights with respect to the shares of common stock underlying the Warrants. We are registering the securities offered hereby pursuant to such registration rights.

This prospectus is part of a registration statement that we have filed with the SEC to register 13,086,151 shares of our common stock issuable upon exercise of the Warrants (the "Selling Stockholder Shares"). The Selling Stockholder 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 Selling Stockholder Shares registered hereunder, or interests therein. This prospectus also relates to the issuance by us of the shares of common stock issuable upon the exercise of Warrants. We will receive proceeds from any exercise of the Warrants for cash.

THE OFFERING

Common stock offered by selling stockholders	13,086,151 shares issuable upon the exercise of the Warrants held by the selling stockholders identified in the “Selling Stockholders” section of this prospectus.
Use of proceeds	We will not receive any proceeds from the sale of the shares of common stock covered by this prospectus. This prospectus also relates to the issuance by us of the shares of common stock issuable upon the exercise of Warrants. We will receive proceeds from any exercise of the Warrants for cash.
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 named in this prospectus may offer and sell up to an aggregate of 13,086,151 shares of our common stock issuable upon the exercise of the Warrants. Throughout this prospectus, when we refer to the shares of our common stock being registered on behalf of the selling stockholders, we are referring to all 13,086,151 shares of common stock that are issuable upon the exercise of the Warrants held by the selling stockholders as of April 26, 2024.

We agreed to file this prospectus pursuant to the Purchase Agreement with the selling stockholders. Additional information with respect to the Purchase Agreement is contained in this prospectus under the heading “Selling Stockholders” and in our Current Report on Form 8-K filed with the SEC on February 29, 2024.

When we refer to the selling stockholders, we are referring to the selling stockholders identified in the “Selling Stockholders” section of this prospectus 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 Annual Report on Form 10-K for the year ended December 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:

- 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, rising interest rates, increased volatility in the debt and equity markets, instability in the global banking system, global health crises and pandemics and geopolitical conflict, 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 I, Item 1A. “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 28, 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 Securities Exchange Act of 1934, as amended (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 at 2722 29th Drive SE, Suite 100, Bothell, WA 98021 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 fiscal year ended December 31, 2023, filed with the SEC on March 28, 2024;
- our Definitive Proxy Statement on [Schedule 14A](#), filed with the SEC on April 26, 2024 (but only with respect to information specifically incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2023);
- our Current Report on Form 8-K filed with the SEC on [February 29, 2024](#) (excluding any information furnished in such report under Items 2.02 and 7.01);
- 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.
22722 29th Drive SE, Suite 100
Bothell, Washington 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 Selling Stockholder 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 Selling Stockholder Shares offered by this prospectus. See "Selling Stockholders" and "Plan of Distribution" below.

This prospectus also relates to the issuance by us of the shares of common stock issuable upon the exercise of Warrants. We will receive proceeds from any exercise of the Warrants for cash.

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

We are registering the Selling Stockholder Shares to permit the resale of these Selling Stockholder Shares by the holders thereof from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the Selling Stockholder Shares offered hereby. We will bear all fees and expenses incident to our obligation to register these Selling Stockholder Shares.

The selling stockholders may sell all or a portion of the Selling Stockholder Shares held by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the Selling Stockholder Shares are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The Selling Stockholder Shares may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions, pursuant to one or more of the following methods:

- on any national securities exchange or quotation service on which the shares may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing or settlement of options, whether such options are listed on an options exchange or otherwise;
- 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;
- short sales made after the date the Registration Statement is declared effective by the SEC;
- broker-dealers may agree with a selling stockholder to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell Selling Stockholder Shares under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the selling stockholders may transfer the Selling Stockholder Shares by other means not described in this prospectus. If the selling stockholders effect such transactions by selling Selling Stockholder Shares to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the Selling Stockholder Shares for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters,

broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the Selling Stockholder Shares or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the Selling Stockholder Shares in the course of hedging in positions they assume. The selling stockholders may also sell shares of common stock short and deliver Selling Stockholder Shares covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge Selling Stockholder Shares to broker-dealers that in turn may sell such Selling Stockholder Shares.

The selling stockholders may pledge or grant a security interest in some or all of the Selling Stockholder Shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the Selling Stockholder Shares from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the Selling Stockholder Shares in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

To the extent required by the Securities Act and the rules and regulations thereunder, the selling stockholders and any broker-dealer participating in the distribution of Selling Stockholder Shares may be deemed to be “underwriters” within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the Selling Stockholder Shares, a prospectus supplement, if required, will be distributed, which will set forth the aggregate amount of Selling Stockholder Shares being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholders and any discounts, commissions or concessions allowed or re-allowed or paid to broker-dealers.

Under the securities laws of some states, Selling Stockholder Shares may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states Selling Stockholder Shares offered hereby may not be sold unless such Selling Stockholder Shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the Selling Stockholder Shares registered pursuant to the registration statement of which this prospectus forms a part.

The selling stockholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act (“Regulation M”), which may limit the timing of purchases and sales of any Selling Stockholder Shares by the selling stockholders and any other participating person. To the extent applicable, Regulation M may also restrict the ability of any person engaged in the distribution of the Selling Stockholder Shares to engage in market-making activities with respect to the Selling Stockholder Shares. All of the foregoing may affect the marketability of the Selling Stockholder Shares and the ability of any person or entity to engage in market-making activities with respect to the Selling Stockholder Shares.

Once sold under the registration statement of which this prospectus forms a part, the Selling Stockholder Shares offered hereby will be freely tradable in the hands of persons other than our affiliates.

SELLING STOCKHOLDERS

The Selling Stockholder Shares being offered by the selling stockholders under this prospectus consist of shares issuable to the selling stockholders upon exercise of the Warrants. Pursuant to the Purchase 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 Purchase Agreement.

The table below lists the selling stockholders and other information regarding their beneficial ownership (as determined under Section 13(d) of the Exchange Act and the rules and regulations thereunder) of our common stock as of April 19, 2024. Under Section 13(d) of the Exchange Act, beneficial ownership generally includes voting or investment power with respect to securities, including any securities that grant the holder the right to acquire shares of common stock within 60 days of the date of determination. These shares are deemed to be outstanding for the purpose of computing the percentage ownership of the person holding those securities, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. The percentage ownership data is based on 34,251,911 shares of our common stock issued and outstanding as of April 19, 2024 (as reflected in the records of our stock transfer agent). The Warrants cannot be exercised by a Warrant holder if, after giving effect thereto, such Warrant holder would beneficially own more than 4.99% (or, at the election of the holder, 9.99% or 19.99%) of our outstanding common stock. The table below gives effect to the selling stockholder's applicable beneficial ownership limitation.

We have prepared the table below based on information furnished to us by or on behalf of the selling stockholders. The second column of the table lists the number of shares of common stock beneficially owned by the selling stockholders as of April 19, 2024. The third column of the table lists the Selling Stockholder Shares being offered under this prospectus by the selling stockholders or by those persons or entities to whom they transfer, donate, devise, pledge or distribute their Selling Stockholder Shares or by other successors in interest.

Because, among other things, the exercise of the Warrants is at the option of the holders, the number of shares of common stock that will actually be issued to the selling stockholders pursuant to the Warrants may be more or less than the number of Selling Stockholder Shares being offered by this prospectus. In addition, the Selling Stockholder 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 Selling Stockholder Shares in this offering and because there are currently no agreements, arrangements or undertakings with respect to the sale of any of the Selling Stockholder Shares, we cannot estimate the number of Selling Stockholder Shares the selling stockholders will sell under this prospectus. The fourth column of the table assumes the sale of all of the Selling Stockholder Shares offered by the selling stockholders pursuant to this prospectus.

Except for the ownership of the Selling Stockholder Shares and Warrants purchased from us in the February 2024 private placement and the entry into the Purchase Agreement to which this prospectus relates, no selling stockholders have had any material relationship with us within the past three years.

Unless otherwise indicated in the footnotes below, we believe that the selling stockholders have sole voting and investment power with respect to all shares of our common stock beneficially owned by them. Since the date on which they provided us with the information below, the selling stockholders may have sold, transferred or otherwise disposed of some or all of their shares in transactions exempt from the registration requirements of the Securities Act.

Name of Selling Stockholder	Shares of Common Stock Owned Prior to Offering		Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus	Shares of Common Stock Owned After Offering	
	Number	Percentage (%)		Number	Percentage (%)
ADAR1 Partners, LP ⁽¹⁾	1,750,000	4.98	875,000	875,000	2.49
Altium Growth Fund, LP ⁽²⁾	1,800,000	5.12	900,000	900,000	2.56

Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B ⁽³⁾	400,000	1.16	200,000	200,000	*
Alyeska Master Fund, L.P. ⁽⁴⁾	942,000	2.71	471,000	471,000	1.36
Entities affiliated with Anson Advisors, Inc. ⁽⁵⁾	1,500,000	4.29	750,000	750,000	2.14
John Bencich ⁽⁶⁾	86,724	*	10,000	76,724	*
Brio Capital Master Fund Ltd. ⁽⁷⁾	965,545	2.81	163,489	802,056	2.33
Entities affiliated with Contrarian Alpha Management, LLC ⁽⁸⁾	2,348,177	6.84	100,000	2,248,177	6.54
CVI Investments, Inc. ⁽⁹⁾	2,268,229	4.99	750,000	1,518,229	4.34
District 2 Capital Fund LP ⁽¹⁰⁾	400,000	1.16	200,000	200,000	*
Franklin Strategic Series - Franklin Biotechnology Discovery Fund ⁽¹¹⁾	4,362,050	11.97	2,181,025	2,181,025	5.99
Lind Global Fund II LP ⁽¹²⁾	400,200	1.16	200,100	200,100	*
Lytton-Kambara Foundation ⁽¹³⁾	400,000	1.16	200,000	200,000	*
Entities affiliated with Nantahala Capital Management ⁽¹⁴⁾	1,308,000	3.75	654,000	654,000	1.87
Entities affiliated with Propel Bio Partners ⁽¹⁵⁾	4,634,117	9.99	2,181,025	2,453,092	6.73
Sofinnova Investments, Inc. ⁽¹⁶⁾	3,000,000	8.39	1,500,000	1,500,000	4.20
Sopharma AD ⁽¹⁷⁾	2,182,820	6.18	1,090,512	1,092,308	3.09
Richard Stewart ⁽¹⁸⁾	30,626	*	10,000	20,626	*
Stonepine Capital, LP ⁽¹⁹⁾	1,300,000	3.72	650,000	650,000	1.86

* Represents beneficial ownership of less than one percent of the outstanding shares of our common stock.

- (1) The shares of common stock beneficially owned prior to this offering include (i) 875,000 shares of common stock and (ii) 875,000 shares of common stock issuable upon exercise of Warrants held by ADAR1 Partners, LP. The address of ADAR1 Partners, LP is 3503 Wild Cherry Drive, Building 9, Austin, TX 78738.
- (2) The shares of common stock beneficially owned prior to this offering include (i) 900,000 shares of common stock and (ii) 900,000 shares of common stock issuable upon exercise of Warrants held by Altium Growth Fund, LP. The address for Altium Growth Fund, LP is 152 W 57th Street, New York, NY 10019.
- (3) The shares of common stock beneficially owned prior to this offering include (i) 200,000 shares of common stock and (ii) 200,000 shares of common stock issuable upon exercise of Warrants held by Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B ("Alto"). Ayrton Capital LLC, the investment manager to Alto, has discretionary authority to vote and dispose of the shares held by Alto and may be deemed to be the beneficial owner of these shares. Waqas Khatri, in his capacity as Managing Member of Ayrton Capital LLC, may also be deemed to have investment discretion and voting power over the shares held by Alto. Ayrton Capital LLC and Mr. Khatri each disclaim any beneficial ownership of these shares. The address of Ayrton Capital LLC is 55 Post Rd West, 2nd Floor, Westport, CT 06880.
- (4) The shares of common stock beneficially owned prior to this offering include (i) 471,000 shares of common stock and (ii) 471,000 shares of common stock issuable upon exercise of Warrants held by Alyeska Master Fund, L.P. ("Alyeska"). Alyeska Investment Group, L.P., the investment manager of Alyeska, has voting and investment control of the shares held by Alyeska. Anand Parekh is the Chief Executive Officer of Alyeska Investment Group, L.P. and may be deemed to be the beneficial owner of such shares. Mr. Parekh, however, disclaims any beneficial ownership of the shares held by Alyeska. The registered address of Alyeska Master Fund, L.P. is at c/o Maples Corporate Services Limited, P.O. Box 309, Ugland House, South Church Street George Town, Grand Cayman, KY1-1104, Cayman Islands. Alyeska Investment Group, L.P. is located at 77 W. Wacker, Suite 700, Chicago, IL 60601.
- (5) The shares of common stock beneficially owned prior to this offering include (i) 585,000 shares of common stock held by Anson Investments Master Fund LP ("AIMF"), (ii) 165,000 shares of common stock held by Anson East Master Fund LP ("AEMF"), (iii) 585,000 shares of common stock issuable upon exercise of Warrants held by AIMF and (iv) 165,000 shares of common stock issuable upon exercise of Warrants

- held by AEMF. Amin Nathoo is a director of Anson Advisors, Inc. and shares voting and dispositive power over the shares held by each of AIMF and AEMF. The address of AIMF and AEMF is 181 Bay St. #4200, Toronto, ON M5J 2T3.
- (6) The shares of common stock beneficially owned prior to this offering include (i) 76,724 shares of common stock and (ii) 10,000 shares of common stock issuable upon exercise of Warrants held by John Benchich.
 - (7) The shares of common stock beneficially owned prior to this offering include (i) 639,886 shares of common stock and (ii) 325,569 shares of common stock issuable upon exercise of Warrants held by Brio Capital Master Fund Ltd. The address for Brio Capital Master Fund Ltd. is Brio Capital Management LLC, 100 Merrick Road, Suite 401W, Rockville Centre, NY 11570.
 - (8) The shares of common stock beneficially owned prior to this offering include (i) 269,800 shares of common stock held by Contrarian Alpha, LP ("CA"), (ii) 1,318,918 shares of common stock held by Contrarian Achieve SPV LP ("CAS"), (iii) 100,000 shares of common stock issuable upon exercise of Warrants held by CA and (iv) 659,459 shares of common stock issuable upon exercise of Warrants held by CAS. Parker Quillen is a manager of Contrarian Alpha Management, LLC and shares voting and dispositive power over the shares held by each of CA and CAS. The address of CA and CAS is 22 Fieldview Lane, East Hampton, NY 11937.
 - (9) The shares of common stock beneficially owned prior to this offering include (i) 1,295,729 shares of common stock and (ii) 972,500 shares of common stock issuable upon exercise of Warrants held by CVI Investments, Inc. ("CVI"). Heights Capital Management, Inc., the authorized agent of CVI, has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc., may also be deemed to have investment discretion and voting power over the shares held by CVI. Mr. Kobinger disclaims any such beneficial ownership of the shares. CVI Investments, Inc. is affiliated with one or more FINRA member, none of whom are currently expected to participate in the sale pursuant to the prospectus contained in the Registration Statement of Shares purchased by the Investor in this Offering. The address of CVI is c/o Heights Capitals Management, Inc., 101 California Street, Suite 3250, San Francisco, CA 94111. The number in the column "Percentage (%)—Shares of Common Stock Owned Prior to the Offering" gives effect to the provision of the Warrants limiting the ability of a Warrant holder to exercise its Warrants if, after giving effect to such exercise, such Warrant holder would beneficially own more than 4.99% of our outstanding common stock.
 - (10) The shares of common stock beneficially owned prior to this offering include (i) 200,000 shares of common stock and (ii) 200,000 shares of common stock issuable upon exercise of Warrants held by District 2 Capital Fund LP. The address of District 2 Capital Fund LP is 14 Wall Street, 2nd Floor, Huntington, NY 11743.
 - (11) The shares of common stock beneficially owned prior to this offering include (i) 2,181,025 shares of common stock and (ii) 2,181,025 shares of common stock issuable upon exercise of Warrants held by Franklin Strategic Series - Franklin Biotechnology Discovery Fund. The address for Franklin Strategic Series - Franklin Biotechnology Discovery Fund is One Franklin Parkway, San Mateo, CA 94403.
 - (12) The shares of common stock beneficially owned prior to this offering include (i) 200,100 shares of common stock and (ii) 200,100 shares of common stock issuable upon exercise of Warrants held by Lind Global Fund II LP. The address for Lind Global Fund II LP is 444 Madison Avenue, Floor 41, New York, NY 10022.
 - (13) The shares of common stock beneficially owned prior to this offering include (i) 200,000 shares of common stock and (ii) 200,000 shares of common stock issuable upon exercise of Warrants held by Lytton-Kambara Foundation. The address of Lytton-Kambara Foundation is 467 Central Park West, 17-A, New York, NY 10025.
 - (14) The shares of common stock beneficially owned prior to this offering include (i) 133,100 shares of common stock held by Nantahala Capital Partners Limited Partnership ("NCP"), (ii) 116,300 shares of common stock held by NCP RFM LP ("NCP RFM"), (iii) 404,600 shares of common stock held by Blackwell Partners LLC - Series A ("BP" and, together with NCP and NCP RFM, the "Nantahala Entities"), (iv) 133,100 shares of common stock issuable upon exercise of Warrants held by NCP, (v) 116,300 shares of common stock issuable upon exercise of Warrants held by NCP RFM and (vi) 404,600 shares of common stock issuable upon exercise of Warrants held by BP. Nantahala Capital Management, LLC is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of such securities on behalf of the selling stockholder as a General Partner, Investment Manager, or Sub-Advisor and would be considered the beneficial owner of such securities. The above shall not be deemed to be an admission by the record owners or the selling stockholder that they are themselves beneficial owners of these securities for purposes of Section 13(d) of the Exchange Act or any other purpose. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the Nantahala Entities. The address for the Nantahala Entities is 130 Main Street, 2nd Floor, New Canaan, CT 06840.
 - (15) The shares of common stock beneficially owned prior to this offering include (i) 348,660 shares of common stock held by Propel Bio Partners L.P. ("PBP"), (ii) 1,886,587 shares of common stock held by Propel Bio SPV 2, LLC ("PBS"), (iii) 294,438 shares of common stock issuable upon exercise of Warrants held by PBP, (iv) 1,886,587 shares of common stock issuable upon exercise of Warrants held by PBS, and (v) 217,845 shares of common stock held by Simplify Propel Opportunities ETF ("SURI ETF"). Leen Kawas is a managing member of Propel Bio Partners L.P. and shares voting and dispositive power over the shares held by each of PBP, PBS and SURI ETF. The address of PBP and PBS is 11620 Wilshire Blvd., Suite 350, Los Angeles, CA 90025, and the address for SURI ETF is 222 Broadway, Floor 22, New York, NY 10038. The number in the column "Percentage (%)—Shares of Common Stock Owned Prior to the Offering" gives effect to the provision of
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- the Warrants limiting the ability of a Warrant holder to exercise its Warrants if, after giving effect to such exercise, such Warrant holder would beneficially own more than 9.99% of our outstanding common stock.
- (16) The shares of common stock beneficially owned prior to this offering include (i) 1,500,000 shares of common stock and (ii) 1,500,000 shares of common stock issuable upon exercise of Warrants held by Sofinnova Investments, Inc. The address for Soginnova Investments, Inc. is 3000 Sand Hill Road, Building 4, Suite 250, Menlo Park, CA 94025.
 - (17) The shares of common stock beneficially owned prior to this offering include (i) 1,092,308 shares of common stock and (ii) 1,090,512 shares of common stock issuable upon exercise of Warrants held by Sopharma AD. The address of Sopharma AD is 16, Iliensko Shosse Street, Sofia 1220, Bulgaria. The number in the column "Percentage (%)—Shares of Common Stock Owned Prior to the Offering" gives effect to the provision of the Warrants limiting the ability of a Warrant holder to exercise its Warrants if, after giving effect to such exercise, such Warrant holder would beneficially own more than 4.99% of our outstanding common stock.
 - (18) The shares of common stock beneficially owned prior to this offering include (i) 20,626 shares of common stock and (ii) 10,000 shares of common stock issuable upon exercise of Warrants held by Richard Stewart.
 - (19) The shares of common stock beneficially owned prior to this offering include (i) 650,000 shares of common stock and (ii) 650,000 shares of common stock issuable upon exercise of Warrants held by Stonepine Capital, LP. The address of Stonepine Capital, LP is 909 NW Bond Street, Suite 204, Bend, OR 97703.

We have entered into the Purchase Agreement with the selling stockholders party thereto pursuant to which, among other things, we have provided them with certain registration rights and agreed to pay certain expenses and indemnify them from certain liabilities in connection with this offering. For more information, see our current report on Form 8-K filed with the SEC on February 29, 2024.

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	\$ 8,633
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.
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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	Exhibit Description	Incorporated by Reference			Filed 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	Securities Purchase Agreement, dated as of February 28, 2024, by and among Achieve Life Sciences, Inc. and the purchasers identified on the signature pages thereto	8-K	033-80623	10.1	2/29/2024	
4.3	Form of Common Stock Warrant	8-K	033-80623	4.1	2/29/2024	
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

* 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.

** To be filed in accordance with the requirements of Section 305(b)(2) of the Trust Indenture Act of 1939 and Rule 5b-3 thereunder.

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 April 26, 2024.

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.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ John Bencich</u> John Bencich	Chief Executive Officer and Director (Principal Executive Officer and Principal Financial Officer)	April 26, 2024
<u>/s/ Jerry Wan</u> Jerry Wan	Senior Director of Accounting Operations (Principal Accounting Officer)	April 26, 2024
<u>/s/ Richard Stewart</u> Richard Stewart	Executive Chairman and Director	April 26, 2024
<u>/s/ Cindy Jacobs</u> Cindy Jacobs	Director	April 26, 2024
<u>/s/ Bridget Martell</u> Bridget Martell	Director	April 26, 2024
<u>/s/ Vaughn Himes</u> Vaughn Himes	Director	April 26, 2024
<u>/s/ Stuart Duty</u> Stuart Duty	Director	April 26, 2024
<u>/s/ Thomas King</u> Thomas King	Director	April 26, 2024
<u>/s/ Thomas Sellig</u> Thomas Sellig	Director	April 26, 2024

April 26, 2024

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

Re: Registration Statement on Form S-3

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 April 26, 2024 (the “*Registration Statement*”), in connection with the registration under the Securities Act of 1933, as amended (the “*Securities Act*”) of an aggregate of 13,086,151 shares of common stock (the “*Common Stock*”), par value \$0.001 per share (the “*Shares*”), for offer and resale by the selling stockholders described and listed in the Registration Statement (the “*Selling Stockholders*”), consisting of 13,086,151 Shares issuable by the Company to the Selling Stockholders upon the exercise of (a) currently outstanding common stock warrants issued by the Company to the Selling Stockholders (the “*Initial Warrants*”) or (b) pre-funded warrants that may be issued by the Company upon the exercise of the Initial Warrants (the “*Pre-Funded Warrants*” and collectively with the Initial Warrants, the “*Warrants*”). 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*”).

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 (the “*Opinion Certificate*”). 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 opinions expressed below, we have assumed that, (i) at or prior to the time of the issuance and delivery of the Shares there will not have occurred any change in the law or the facts affecting the validity of the Shares, (ii) at the time of the offer, issuance and sale of the Shares, no stop order suspending the Registration Statement's effectiveness will have been issued and remain in effect, (iii) no future amendments will be made to the Company's current certificate of incorporation (as amended from time to time, the "***Certificate of Incorporation***"), or the Company's bylaws that would be in conflict with or inconsistent with the Company's right and ability to issue the Shares, (iv) at the time of the issuance and sale of the Shares, the Company will be validly existing as a corporation and in good standing under the laws of the State of Delaware and (v) at the time of each exercise of the Warrants, the Company will have a sufficient number of authorized and unissued shares of the Common Stock available for issuance under the Certificate of Incorporation to permit full exercise of each of the Warrants in accordance with their terms without the breach or violation of any other agreement, commitment or obligation of the Company.

We express no opinion regarding the effectiveness of any waiver or stay, extension or of unknown future rights. Further, we express no opinion regarding the effect of provisions relating to indemnification, exculpation or contribution to the extent such provisions may be held unenforceable as contrary to federal or state securities laws or public policy.

Based upon the foregoing, and subject to the qualifications and exceptions contained herein, we are of the following opinion: the Shares, when issued and delivered by the Company upon exercise of the Warrants, in accordance with the terms thereof, will be validly issued, fully paid and non-assessable.

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 the issuance and sale of the Shares subject 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

April 26, 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	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Equity	Common stock, par value \$0.001 per share	Rule 457(c)	13,086,151 ⁽²⁾	\$4.47 ⁽³⁾	\$58,495,094.97	\$0.0001476	\$8,633.88
Total Offering Amounts							\$8,633.88
Total Fees Previously Paid							—
Total Fee Offsets							—
Net Fee Due							\$8,633.88

- (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 13,086,151 shares of the Registrant's Common Stock issuable upon the exercise of warrants or pre-funded warrants to purchase shares of Common Stock of the Registrant.
- (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 \$4.47, the average of the high and low prices of the Common Stock as reported on The Nasdaq Capital Market on April 23, 2024.