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

**FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

DAY ONE BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

83-2415215
(I.R.S. Employer
Identification No.)

**2000 Sierra Point Parkway, Suite 501
Brisbane, CA 94005
(650) 484-0899**

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

Jeremy Bender, Ph.D., M.B.A.
Chief Executive Officer
Day One Biopharmaceuticals Holding Company, LLC
2000 Sierra Point Parkway, Suite 501
Brisbane, CA 94005
(650) 484-0899

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

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

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 earliest 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. (Check one):

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input 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 the Securities Act.

PROSPECTUS



Day One Biopharmaceuticals, Inc.

12,068,959 Shares of Common Stock

This prospectus relates to the registration for potential offer and sale from time to time of up to 12,068,959 shares of our common stock, par value \$0.0001 per share, or the Shares, by the selling stockholders identified in the “*Selling Stockholders*” section of this prospectus. The Shares registered hereunder consist of (i) 10,551,718 outstanding shares held by certain of the selling stockholders and (ii) 1,517,241 shares, or the Warrant Shares, issuable to certain of the selling stockholders upon exercise of certain outstanding pre-funded warrants held by such selling stockholders, or Pre-Funded Warrants.

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. The selling stockholders will bear all underwriting fees, commissions and discounts, if any, attributable to the sales of Shares and any transfer taxes. We will bear all other costs, expenses and fees in connection with the registration of the Shares.

Our common stock is traded on The Nasdaq Global Market under the symbol “DAWN.” On August 26, 2024 the last reported sales price for our common stock was \$14.42 per share.

An investment in our securities involves a high degree of risk. You should carefully consider the information under the heading “[Risk Factors](#)” beginning on page 6 of this prospectus before investing in our securities.

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 date of this prospectus is August 28, 2024

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ABOUT THIS PROSPECTUS

This prospectus is part of an automatic shelf registration statement that we filed with the Securities and Exchange Commission, or the SEC, as a “well-known seasoned issuer” as defined in Rule 405 under the Securities Act of 1933, as amended, or the Securities Act. 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 may be supplemented from time to time by one or more prospectus supplements. Such prospectus supplement may also add, update or change information contained in this prospectus. To the extent there is a conflict between the information contained in this prospectus and the prospectus supplement, you should rely on the information in the prospectus supplement; provided that, if any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in this prospectus or any prospectus supplement—the statement in the document having the later date modifies or supersedes the earlier statement. You should read both this prospectus and any prospectus supplement together with additional information described under the heading “*Where You Can Find More Information*.”

Neither we nor the selling stockholders 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 and the selling stockholders 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.

In this prospectus, unless the context otherwise requires, the terms “Day One,” the “Company,” “we,” “us,” and “our” refer to Day One Biopharmaceuticals, Inc., a Delaware corporation.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus or incorporated by reference in this prospectus from our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 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 “Forward-Looking Statements.”

Our Company

Day One is a biopharmaceutical company founded to address a critical unmet need: the dire lack of therapeutic development in pediatric cancer. Our name was inspired by the “The Day One Talk” that physicians have with patients and their families about an initial cancer diagnosis and treatment plan. We aim to re-envision cancer drug development and redefine what’s possible for all people living with cancer—regardless of age—starting from Day One.

Our lead product, tovorafenib, is an oral, brain-penetrant, highly selective type II rapidly accelerated fibrosarcoma, or RAF, kinase inhibitor. Tovorafenib was granted breakthrough therapy designation by the U.S. Food and Drug Administration, or the FDA, in August 2020 for the treatment of relapsed or refractory low-grade glioma, or pLGG, based on initial results from a Phase 1 trial which showed evidence of rapid anti-tumor activity and durable responses in patients with pLGG. Pediatric low-grade glioma is the most common brain tumor diagnosed in children. While new targeted therapeutic options have recently become available for patients with pLGG, there is no consensual standard of care and a vast majority of patients with pLGG do not yet have access to approved therapies. Tovorafenib received orphan drug designation for the treatment of malignant glioma from the FDA in September 2020 and from the EU Commission for the treatment of glioma in May 2021. Additionally, the FDA granted rare pediatric disease designation to tovorafenib for treatment of low-grade gliomas, or LGGs, harboring an activating RAF alteration in July 2021.

On April 23, 2024, we announced that the FDA approved OJEMDA™ (tovorafenib) for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. The indication was approved under accelerated approval based on response rate and duration of response. With the approval, we received a rare pediatric disease priority review voucher, or PRV, from the FDA. We have commenced the commercial launch of OJEMDA in the United States. OJEMDA is the only systemic therapy for pLGG that offers once-weekly dosing, with or without food, as a tablet or oral suspension.

The accelerated approval of OJEMDA is based on data from the Company’s pivotal open-label Phase 2 FIREFLY-1 trial, which enrolled a total of 137 relapsed or refractory BRAF-altered pLGG patients across two study arms. Arm 1, which accrued 77 patients, was used for the efficacy analyses. Arm 2 provided additional safety data from an incremental 60 patients and was initiated to enable access to OJEMDA once Arm 1 had fully accrued. Details of this trial were presented in November 2023 at the Society for Neuro-Oncology meeting through two oral plenary presentations and in parallel through a publication in Nature Medicine.

The approval of OJEMDA was based, in part, on the major efficacy outcome measure of overall response rate, or ORR, defined as the proportion of patients with complete response, partial response, or PR, or minor response, or MR, by independent review based on Response Assessment in Pediatric Neuro-Oncology Low-Grade Glioma, or RAPNO LGG.

The safety of OJEMDA was evaluated in 137 patients with relapsed or refractory pLGG, with the majority of adverse events being Grade 1 or Grade 2. The most common side effects were rash, hair color changes, tiredness, viral infection, vomiting, headache, fever, dry skin, constipation, nausea, acne and upper respiratory tract infection.

We initiated a pivotal Phase 3 trial, or FIREFLY-2, evaluating tovorafenib as a front-line therapy in patients ages 6 months to 25 years with pLGG in June 2022. The first patient was dosed in FIREFLY-2 in March 2023. To date, patients continue to enroll in the United States, Canada, Europe, Australia and Asia, with approximately 100 sites activated. In June 2024, we announced the following changes to our FIREFLY-2 trial: the primary endpoint of objective response rate will be assessed according to the RAPNO-LGG criteria, key secondary endpoints of progression free survival and duration of response will be assessed according to RAPNO-LGG criteria, new patients will be initiated on a starting dose of 380 mg/m²/dose once weekly, and the addition of a once-monthly carboplatin regime as a fourth standard of care option for arm 2.

On July 23, 2024, we entered into an Exclusive License Agreement, or the Ipsen License Agreement, with Ipsen Pharma SAS, or Ipsen, pursuant to which we will license to Ipsen, on an exclusive basis, the right to commercialize tovorafenib outside the United States.

Our product candidate, pimasertib, is an oral, highly selective small molecule inhibitor of mitogen-activated protein kinase kinases 1 and 2, or MEK, a well-characterized key signaling node in the MAPK pathway. Pimasertib has been studied in more than 10 Phase 1/2 clinical trials in over 850 patients with various tumor types, both as a monotherapy and in combination with standard of care therapies. Published preclinical studies indicated that pimasertib has higher central nervous system penetration than other MEK inhibitors.

We initiated an open-label, multicenter, Phase 1b/2a umbrella master trial, or FIRELIGHT-1, of tovorafenib as a monotherapy or in combination, which consists of two substudies. Substudy 1 is a Phase 2a trial of tovorafenib as a monotherapy in patients 12 years and older with relapsed, progressive, or refractory solid tumors harboring a RAF alteration (RAF fusion or amplification). Despite observing responses with a generally well tolerated therapy, a limited duration of response in this rare patient population was observed. We decided in November 2023 to discontinue this monotherapy substudy and re-direct resources to other programs. Results from the substudy will be shared for presentation or publication after the final dataset becomes available. Substudy 2 is a Phase 1b/2 combination trial of tovorafenib and pimasertib in patients 12 years and older with various MAPK-altered solid tumors. Despite observing some clinical responses, the benefit/risk profile, as well as the market opportunity, did not justify the significant investment required to continue the trial. Moreover, it is clear from competing efforts to combine other Type II RAF inhibitors with MEK inhibitors that the hoped-for therapeutic benefit of the combination was more limited than preclinical studies predicted. We decided in July 2024 to close the program. Results from the substudy will be shared for presentation at a future medical meeting or publication.

In August 2023, we entered into a research collaboration and license agreement, or the Sprint License Agreement, with Sprint Bioscience AB, or Sprint, a Swedish corporation located in Huddinge, Sweden. Under the Sprint License Agreement, Sprint granted to us an exclusive, worldwide license, with the right to grant sublicenses through multiple tiers, to research, develop, and commercialize pharmaceutical products and to engage in research aimed at discovery, optimization and development of Vaccinia Related Kinase 1, or VRK1. VRK1 is a novel target involved in the regulation of cell division and DNA damage repair. Over-expression of VRK1 is linked to poor prognosis in a variety of adult and pediatric cancers, and VRK1 has been identified as a synthetic lethal target in tumors where expression of its paralog, VRK2, is lost. Silencing of VRK2 expression via promoter methylation has been noted in most high-grade gliomas and high-risk neuroblastomas, providing a concrete approach for selecting patients with tumors sensitive to VRK1 inhibition. Preclinical research activities to advance the VRK1 program are ongoing.

In June 2024, we entered into a license agreement, or the MabCare License Agreement, with MabCare Therapeutics, or MabCare, a pharmaceutical corporation located in Shanghai, China. Under the MabCare License Agreement, MabCare granted to us an exclusive worldwide license, excluding Greater China, with the right to grant sublicenses through multiple tiers, under specified patent rights and know-how for the Company to develop, manufacture and commercialize DAY301 (formerly MTX-13 or CB-002). DAY301 is a novel Antibody Drug Conjugate, or ADC, targeting protein-tyrosine kinase 7, or PTK7. In April 2024, the FDA cleared the investigational new drug application for DAY301. In pre-clinical studies, DAY301 showed antitumor activity in a wide range of solid tumors. DAY301 targets PTK7, a highly-conserved, catalytically inactive transmembrane protein that is overexpressed in multiple adult cancers, including esophageal, ovarian, lung, and endometrial cancer, as well as pediatric cancers such as neuroblastoma, rhabdomyosarcoma and osteosarcoma.

Corporate Information

We were formed as a limited liability company under the laws of the State of Delaware in November 2018, under the name Hero Therapeutics Holding Company, LLC. We subsequently changed our name to Day One Therapeutics Holding Company, LLC in December 2018 and to Day One Biopharmaceuticals Holding Company, LLC in March 2020. In connection with our initial public offering, we converted from a Delaware limited liability company to a Delaware corporation and changed our name to Day One Biopharmaceuticals, Inc. Our principal executive offices are located at 2000 Sierra Point Parkway, Suite 501, Brisbane, CA 94005, and our telephone number is (650) 484-0899. Our website address is www.dayonebio.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into, this prospectus. We have included our website address in this prospectus solely as an inactive textual reference. Investors should not rely on any such information in deciding whether to purchase our common stock.

THE OFFERING

Common stock offered by selling stockholders	12,068,959 Shares, which includes (i) 10,551,718 outstanding shares held by certain of the selling stockholders and (ii) 1,517,241 Warrant Shares. See the “ <i>Selling Stockholders</i> ” section of this prospectus.
Use of proceeds	We will not receive any proceeds from the sale of the Shares.
Risk factors	See “ <i>Risk Factors</i> ” included herein, for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Nasdaq Global Market Symbol	DAWN

The selling stockholders named in this prospectus may offer and sell up to an aggregate of 12,068,959 Shares, which includes (i) 10,551,718 shares of common stock held by the selling stockholders and (ii) 1,517,241 Warrant Shares.

We agreed to file this prospectus pursuant to the Registration Rights Agreement, dated as of July 30, 2024, between the Company and the investors listed on the signature pages thereto, or 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 SEC on July 30, 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. You should also consider the risks, uncertainties and assumptions discussed under Part II, Item 1A, “Risk Factors,” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, which is incorporated herein by reference, and 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.

FORWARD-LOOKING STATEMENTS

This prospectus and documents incorporated herein by reference contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained or incorporated herein by reference are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact contained or incorporated herein by reference, including without limitation statements regarding our future results of operations and financial position, business strategy, market size, potential growth opportunities, nonclinical and clinical development activities, efficacy and safety profile of our product candidates, potential therapeutic benefits and economic value of our product candidates, use of net proceeds from our public offerings, our ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of nonclinical studies and clinical trials, commercial collaboration with third parties, and our ability to recognize milestone and royalty payments from commercialization agreements, the potential impact of global business or macroeconomic conditions, including as a result of inflation, rising interest rates, instability in the global banking system, and geopolitical conflict, on our operations, and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, are forward-looking statements. We intend that such forward-looking statements be subject to the safe harbors created thereby.

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 those discussed in Part II, Item 1A, “Risk Factors,” in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2024, as well as those discussed in this prospectus, the documents incorporated by reference into this prospectus and any free writing prospectus. 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, or 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 inspect a copy of the registration statement through the SEC's website, as provided above, or at our principal executive offices, 2000 Sierra Point Parkway, Suite 501, Brisbane, California 94005, during normal business hours.

Information about us is also available at our website at <http://www.dayonebio.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 February 26, 2024;
- our Quarterly Reports on Form 10-Q for the quarters ended [March 31, 2024](#) and [June 30, 2024](#), filed with the SEC on May 6, 2024 and August 2, 2024, respectively;
- our Current Reports on Form 8-K filed with the SEC on [January 17, 2024](#), [March 7, 2024](#), [April 24, 2024](#), [May 24, 2024](#), [May 30, 2024](#), [June 12, 2024](#), [June 18, 2024](#), [July 25, 2024](#) and [July 30, 2024](#);
- the description of our common stock contained in our registration statement on [Form 8-A](#) filed with the SEC on May 24, 2021 under Section 12(b) 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). Written or oral requests for copies should be directed to Day One Biopharmaceuticals, Inc., Attn: Investor Relations, 2000 Sierra Point Parkway, Suite 501, Brisbane, CA 94005, and our telephone number is (650) 484-0899. 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 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. The selling stockholders will bear all underwriting fees, commissions and discounts, if any, attributable to the sales of Shares and any transfer taxes.

PLAN OF DISTRIBUTION

The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling Shares or interests in Shares received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their Shares or interests in Shares on any stock exchange, market or trading facility on which the Shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholders may use any one or more of the following methods when disposing of Shares or interests therein:

- distributions to members, partners, stockholders or other equityholders of the selling stockholders;
- 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 and settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such Shares at a stipulated price per share;
- “at the market” to or through market makers or into an existing market for the Shares;
- in other ways not involving market makers or established trading markets, including direct sales to purchasers or sales effected through agents;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the 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 Shares, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act, amending 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 the Shares in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling stockholders for purposes of this prospectus.

In connection with the sale of our common stock 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 common stock in the course of hedging the positions they assume. The selling stockholders may also sell Shares short and deliver these securities to close out their short positions, or loan or pledge the Shares 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

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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 aggregate proceeds to the selling stockholders from the sale of the Shares offered by them will be the purchase price of the Shares less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of Shares to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the pre-funded warrants by payment of cash, however, we will receive the exercise price of the Pre-Funded Warrants.

The selling stockholders also may resell all or a portion of the Shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule, or another available exemption from the registration requirements under the Securities Act.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the Shares or interests therein may be “underwriters” within the meaning of Section 2(a)(11) of the Securities Act (it being understood that the selling stockholders shall not be deemed to be underwriters solely as a result of their participation in this offering). Any discounts, commissions, concessions or profit they earn on any resale of the Shares may be underwriting discounts and commissions under the Securities Act. Selling stockholders who are “underwriters” within the meaning of Section 2(a)(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the Shares to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agent, dealer or underwriter, and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the Shares may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the Shares may not be sold unless they have been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of Shares in the market and to the activities of the selling stockholders and their affiliates. In addition, to the extent applicable, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the Shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the Shares offered by this prospectus.

We have agreed with the selling stockholders to use commercially reasonable efforts to cause the registration statement of which this prospectus constitutes a part to become effective and to remain continuously effective until the earlier of: (i) the date on which the selling stockholders shall have resold or otherwise disposed of all the Shares covered by this prospectus and (ii) the date on which the Shares covered by this prospectus no longer constitute “Registrable Securities” as such term is defined in the Registration Rights Agreement, such that they may be resold by the selling stockholders without registration.

SELLING STOCKHOLDERS

The Shares consist of (i) outstanding shares held by certain of the selling stockholders and (ii) Warrant Shares issuable to certain of the selling stockholders upon exercise of the Pre-Funded Warrants. 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.

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 August 5, 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 99,842,275 shares of our common stock issued and outstanding as of August 5, 2024, after giving effect to the private placement of the Shares and Pre-Funded Warrants, or the Private Placement. The Pre-Funded Warrants cannot be exercised by a Pre-Funded Warrant holder if, after giving effect thereto, such holder would beneficially own more than 9.99% of our outstanding common stock, or the Beneficial Ownership Limitation. Beneficial ownership as reflected in the selling stockholder table reflects the total number of shares potentially issuable underlying the Pre-Funded Warrants and does not give effect to the 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 August 5, 2024. The third column of the table lists the 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 shares or by other successors in interest.

Because, among other things, the exercise of the Pre-Funded Warrants is at the option of the holders, the number of Warrant Shares that will actually be issued to the selling stockholders pursuant to the Pre-Funded Warrants 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.

To our knowledge, none of the selling stockholders has, or during the three years prior to the date of this prospectus has had, any position, office or other material relationships with us or any of our affiliates, except that (i) we and each selling stockholder are party to the Registration Rights Agreement and (ii) Daniel Becker, who serves as Managing Director at Access Biotechnology, the biopharmaceutical investing arm of Access Industries, Inc. and an affiliate of AI Day1 LLC, served as a member of our Board of Directors from December 2019 through May 23, 2024.

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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 ⁽¹⁾	
	Number	Percentage (%)		Number	Percentage (%)
Fairmount Healthcare Fund II L.P. ⁽²⁾	3,103,448	3.11%	3,103,448	—	*
Braidwell Partners Master Fund LP ⁽³⁾	4,824,053	4.83%	1,551,724	3,272,329	3.28%
Entities affiliated with EcoR1 Capital L.P. ⁽⁴⁾	862,068	*	862,068	—	*
Entities affiliated with Franklin Advisers, Inc. ⁽⁵⁾	862,068	*	862,068	—	*
Entities affiliated with Maverick Capital, Ltd. ⁽⁶⁾	2,119,013	2.12%	862,068	1,256,945	1.26%
Entities affiliated with Frazier Life Sciences Management L.P. ⁽⁷⁾	689,655	*	689,655	—	*
Deerfield Partners, L.P. ⁽⁸⁾	2,631,922	2.64%	689,655	1,942,267	1.95%
Estuary Master Fund LP ⁽⁹⁾	2,926,894	2.93%	620,689	2,306,205	2.31%
Adage Capital Partners, L.P. ⁽¹⁰⁾	1,251,724	1.25%	551,724	700,000	*
Entities advised or subadvised by T. Rowe Price Associates, Inc. ⁽¹¹⁾	2,165,923	2.17%	344,827	1,821,096	1.82%
Entities affiliated with Wellington Management Company LLP ⁽¹²⁾	172,413	*	172,413	—	*
PFM Healthcare Master Fund, L.P. ⁽¹³⁾	573,763	*	137,931	435,832	*
Entities affiliated with First Turn Management, LLC ⁽¹⁴⁾	1,051,326	1.05%	103,448	947,878	*
AI Day1 LLC ⁽¹⁵⁾	13,756,908	12.95%	827,586	12,929,322	12.95%
Entities affiliated with Baker Bros. Advisors LP ⁽¹⁶⁾	689,655	*	689,655	—	*

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

- (1) The selling stockholders may offer and sell all or part of the Shares covered by this prospectus, and no assumption can be made as to the actual number of shares of common stock that will be held by the selling stockholders after the completion of this offering.
- (2) The shares of common stock registered hereby were acquired in the Private Placement. Fairmount Funds Management LLC, or Fairmount, has voting and dispositive power over the shares held by Fairmount Healthcare Fund II L.P. The general partner of Fairmount is Fairmount Funds Management GP LLC, or Fairmount GP, of which Peter Harwin and Tomas Kiselak are the managing members. Fairmount, Fairmount GP, Mr. Harwin, and Mr. Kiselak disclaim beneficial ownership of any of the reported securities, except to the extent of their pecuniary interest therein. The address these entities is 200 Barr Harbor Drive, Suite 400, West Conshohocken, PA 19428.
- (3) The shares of common stock registered hereby were acquired in the Private Placement and are held directly by Braidwell Partners Master Fund LP, or Braidwell Partners. Braidwell LP, or the Braidwell Investment Manager, is the investment manager of Braidwell Partners. The general partner of Braidwell Partners is Braidwell GP LLC, or the Braidwell GP. Braidwell Management LLC, or the Braidwell IM GP, is the managing member of the Braidwell GP and the general partner of the Braidwell GP. Alexander T. Karnal and Brian J. Kreiter, or the Co-Founders and, together with Braidwell Partners, the Braidwell Investment Manager, the Braidwell GP and the Braidwell IM GP, the Braidwell Parties, are the managing members of the Braidwell IM GP. Each of the Braidwell Parties may be deemed to share voting and investment power

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with respect to the securities held by Braidwell Partners. The Braidwell Parties disclaim beneficial ownership of the shares held by Braidwell Partners except to the extent of their pecuniary interests therein. The address of Braidwell Partners is c/o Maples Corporate Services Limited, P.O. Box 309, Uglund House, Grand Cayman, KY1-1104 Cayman Islands, and the address of the other Braidwell Parties is c/o Braidwell LP, One Harbor Point, 2200 Atlantic Street, Stamford, CT 06902.

- (4) The shares of common stock registered hereby were acquired in the Private Placement and consist of: (i) 811,206 shares of common stock held by EcoR1 Capital Fund Qualified, L.P. and (ii) 50,862 shares of common stock held by EcoR1 Capital Fund, L.P., or collectively, the EcoR1 Entities. EcoR1 Capital, LLC, or EcoR1, is the general partner of the EcoR1 Entities. Oleg Nodelman is the control person of EcoR1 and may be deemed to share dispositive voting power over the shares held by the EcoR1 Capital Funds. Mr. Nodelman and EcoR1 both disclaim beneficial ownership of all shares except to the extent of their pecuniary interest therein. The address for these entities is 357 Tehama Street #3, San Francisco, CA 94103.
- (5) The shares of common stock registered hereby were acquired in the Private Placement and consist of: (i) 227,068 shares of common stock held by Franklin Strategic Series – Franklin Biotechnology Discovery Fund, or FSS, (ii) 399,900 shares of common stock held by Franklin Templeton Investment Funds – Franklin Biotechnology Discovery Fund, or FTIF, and (iii) 235,100 shares of common stock held by Franklin Strategic Series – Franklin Small Cap Growth Fund, or FSCGF. Franklin Advisers, Inc., or Franklin, of which Evan McCulloch is the Vice President, as investment adviser, has voting and dispositive power over the shares held by FSS, FTIF, and FSCGF. Franklin and Mr. McCulloch disclaim beneficial ownership of such securities, except to the extent of any pecuniary interest therein. The address of these entities is One Franklin Parkway, San Mateo, CA 94403.
- (6) The shares of common stock registered hereby were acquired in the Private Placement and consist of: (i) 167,437 shares of common stock held by Maverick Fund II, Ltd., (ii) 219,563 shares of common stock held by Maverick Fund USA, Ltd., (iii) 173,092 shares of common stock held by Maverick HP, LP, (iv) 207,300 shares of common stock held by Maverick Long Enhanced Fund, Ltd., and (v) 94,676 shares of common stock held by Maverick Long Fund, Ltd. Maverick Capital, Ltd. is an investment adviser registered under Section 203 of the Investment Advisers Act of 1940 and, as such, may be deemed to have beneficial ownership of the shares held by Maverick Fund II, Ltd., Maverick Fund USA, Ltd., Maverick HP, LP, Maverick Long Enhanced Fund, Ltd., and Maverick Long Fund, Ltd. through the investment discretion it exercises over these accounts. Maverick Capital Management, LLC is the general partner of Maverick Capital, Ltd. Lee S. Ainslie III is the manager of Maverick Capital Management, LLC who possesses sole investment discretion pursuant to Maverick Capital Management, LLC's regulations. The address of these entities is c/o Maverick Capital, Ltd., Attn: General Counsel, 1900 N. Pearl Street, 20th Floor, Dallas, TX 75201.
- (7) The shares of common stock registered hereby were acquired in the Private Placement and consist of: (i) 683,172 shares of common stock held by Frazier Life Sciences Public Fund, L.P., or FLSPF, (ii) 3,173 shares of common stock held by Frazier Life Sciences X, L.P., or FLS X, and (iii) 3,310 shares of common stock held by Frazier Life Sciences XI, L.P., or FLS XI. FHMLSP, L.P. is the general partner of FLSPF and FHMLSP, L.L.C. is the general partner of FHMLSP, L.P. Albert Cha, James N. Topper, Patrick J. Heron and James Brush are the managing directors of FHMLSP, L.L.C. and therefore share voting and investment power over the shares held by FLSPF. Dr. Cha, Dr. Topper, Mr. Heron and Dr. Brush disclaim beneficial ownership of the shares held by FLSPF except to the extent of their pecuniary interests in such shares, if any. FHMLS X, L.P. is the general partner of FLS X, and FHMLS X, L.L.C. is the general partner of FHMLS X, L.P. Mr. Heron and Dr. Topper are the members of FHMLS X, L.L.C. and therefore share voting and investment power over the shares held by FLS X. Dr. Topper and Mr. Heron disclaim beneficial ownership of the shares held by FLS X except to the extent of their pecuniary interests in such shares, if any. FHMLS XI, L.P. is the general partner of FLS XI, and FHMLS XI, L.L.C. is the general partner of FHMLS XI, L.P. Mr. Heron, Dr. Topper and Daniel Estes are the members of FHMLS XI, L.L.C. and therefore share voting and investment power over the shares held by FLS XI. Dr. Topper, Mr. Heron and Mr. Estes disclaim beneficial ownership of the shares held by FLS XI except to the extent of their pecuniary interests in such shares, if any. The address of these entities is 1001 Page Mill Road, Building 4, Suite B, Palo Alto, CA 94304.

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- (8) The shares of common stock registered hereby were acquired in the Private Placement. The general partner of Deerfield Partners is Deerfield Mgmt, L.P. Deerfield Management Company, L.P. is the investment manager of Deerfield Partners. James E. Flynn is the sole member of the general partner of each of Deerfield Mgmt, L.P. and Deerfield Management Company, L.P. Each of Deerfield Management Company, L.P., Deerfield Mgmt, L.P. and Mr. Flynn may be deemed to beneficially own the shares of Common Stock held by Deerfield Partners. The address of these entities is 345 Park Avenue South, Floor 12, New York, NY 10010.
- (9) The shares of common stock registered hereby were acquired in the Private Placement. Estuary Capital Management, or Estuary, has voting and dispositive power over the shares held by Estuary Master Fund LP. The control person of Estuary is Jeffrey Anecchino. Estuary and Mr. Anecchino disclaim beneficial ownership of any of the reported securities, except to the extent of their pecuniary interest therein. The address of each of these entities is 308 Walker Avenue, Wayzata, MN 55391.
- (10) The shares of common stock registered hereby were acquired in the Private Placement. Bob Atchinson and Phillip Gross are the managing members of Adage Capital Advisors, L.L.C., which is the managing member of Adage Capital Partners GP, L.L.C., which is the general partner of Adage Capital Partners, L.P., and each such person or entity, as the case may be, has shared voting and/or investment power over the securities held by Adage Capital Partners, L.P. and may be deemed the beneficial owner of such shares, and each such person or entity, as the case may be, disclaims beneficial ownership of such securities except to the extent of their respective pecuniary interest therein. The address of these entities is c/o Adage Capital Partners, L.P., 200 Clarendon St., 52nd Floor, Boston, MA 02116.
- (11) The shares of common stock registered hereby were acquired in the Private Placement and consist of: (i) 272,558 shares of common stock held by T. Rowe Price New Horizons Fund, Inc., (ii) 58,622 shares of common stock held by T. Rowe New Horizons Trust, (iii) 2,755 shares of common stock held by T. Rowe Price U.S. Equities Trust, and (iv) 10,892 shares of common stock held by New York City Deferred Compensation Plan, or collectively, the T. Rowe Entities. T. Rowe Price Associates, Inc., or TRPA, serves as investment adviser or subadvisor, as applicable, with power to direct investments and/or sole power to vote the securities owned by the T. Rowe Entities. Therefore, TRPA may be deemed to be the beneficial owner of all of the shares held by the T. Rowe Entities but disclaims beneficial ownership of such shares. TRPA is a wholly owned subsidiary of T. Rowe Price Group, Inc., which is a publicly traded financial services holding company. The address of these entities is 100 East Pratt Street, Baltimore, MD 21202.
- (12) The shares of common stock registered hereby were acquired in the Private Placement and consist of: (i) 4,907 shares of our common stock held by Fiducian Technology Fund, (ii) 74,420 shares of our common stock held by Wellington Biotechnology Long/Short Fund, L.P., (iii) 60,821 shares of our common stock held by Wellington Biotechnology Long/Short Fund (Bermuda) L.P. and (iv) 32,265 shares of our common stock held by Wellington Trust Company, National Association Multiple Collective Investment Funds Trust, Biotechnology Portfolio, or collectively, the Wellington Entities. Wellington Management Company LLP, or WMC, has the power to dispose of the securities pursuant to WMC's capacity as investment advisor on behalf of the Wellington Entities. WMC is a subsidiary of Wellington Management Group LLP, or WMG. WMG is a Massachusetts limited liability partnership, privately held by 204 partners (as of January 1, 2024). There are no external entities with any ownership interest in the firm. No single partner owns or has the right to vote more than 5% of WMC's capital. Additional information about WMC is available in its Form ADV filed with the SEC. The address of these entities is 280 Congress Street, Boston, MA 02210.
- (13) The shares of common stock registered hereby were acquired in the Private Placement. Brian Grossman, as portfolio manager of PFM Healthcare Master Fund, L.P., has voting and dispositive power over the shares held by PFM Healthcare Master Fund, L.P. Mr. Grossman disclaims beneficial ownership of any of the reported securities, except to the extent of their pecuniary interest therein. The address of these entities is 475 Sansome Street, Suite 1720, San Francisco, CA 94111.
- (14) The shares of common stock registered hereby were acquired in the Private Placement and consist of: (i) 54,610 shares of our common stock held by First Turn, LP and (ii) 48,838 shares of our common stock held by Wilson Fund SPC, Ltd. – NicHealth Separate Account SP, or collectively, the First Turn Entities. First Turn Management LLC, or First Turn, has voting and dispositive power over the shares held by the First

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Turn Entities. Lisa Wheatley is the managing partner of First Turn and may be deemed to share dispositive voting power over the shares held by the First Turn Entities. Ms. Wheatley and First Turn both disclaim beneficial ownership of all shares except to the extent of their pecuniary interest. The address for these entities is 1155 Camino Del Mar, Suite 734, Del Mar, CA 92014.

- (15) The shares of common stock registered hereby consist of 827,586 Warrant Shares issuable upon the exercise of the Pre-Funded Warrants held by AI Day1 LLC. The share ownership numbers and percentages in the table reflect the Beneficial Ownership Limitation. Access Industries Management, LLC, or Access, has voting and dispositive power over the shares held by AI Day1 LLC. The control person of Access is Len Blavatnik. Access and Mr. Blavatnik disclaim beneficial ownership of any of the reported securities, except to the extent of their pecuniary interest therein. The address of these entities is 40 West 57th Street, 28th Floor, New York, NY 10019.
- (16) The shares of common stock registered hereby consist of: (i) 58,275 Warrant Shares issuable upon the exercise of the Pre-Funded Warrants held by 667, L.P. and (ii) 631,380 Warrant Shares issuable upon the exercise of the Pre-Funded Warrants held by Baker Brothers Life Sciences, L.P., or collectively, the BBA Entities. The exercise of the Pre-Funded Warrants held by the BBA Entities into common stock is subject to a beneficial ownership limitation of 9.99%. Baker Bros. Advisors LP, or BBA, is the investment adviser to the BBA Funds and has the sole voting and investment power with respect to the securities held by the BBA Funds and thus may be deemed to beneficially own such securities. Baker Bros. Advisors (GP) LLC, or BBA GP, is the sole general partner of BBA and thus may be deemed to beneficially own the securities held by the BBA Entities. The managing members of BBA GP are Julian C. Baker and Felix J. Baker, who may be deemed to beneficially own the securities held by the BBA Entities. Felix J. Baker, BBA and BBA GP disclaim beneficial ownership of all shares held by the BBA Entities, except to the extent of their indirect pecuniary interest therein. The business address of these entities is 860 Washington Street, 3rd Floor, New York, NY 10014.

LEGAL MATTERS

Fenwick & West LLP, San Francisco, California, 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 as of December 31, 2023 and for the year ended December 31, 2023 and management's assessment of the effectiveness of internal control over financial reporting (which is included in Management's Annual Report on Internal Control over Financial Reporting) as of December 31, 2023 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.

Our financial statements as of December 31, 2022 and 2021, and for each of its fiscal years in the two-year period ended December 31, 2022, included in our Annual Report on Form 10-K for the year ended December 31, 2023, incorporated by reference herein has been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon. Such financial statements are incorporated by reference in this prospectus in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

PART II**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:

SEC registration fee	\$24,885.86	
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 Officers and Directors

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 a provision that eliminates, to the fullest extent permitted by law, the personal liability of a directors for monetary damages resulting from breach of his or her fiduciary duties as a director, except for liability:

- for any breach of the director's duty of loyalty to the Registrant or its stockholders;
- for 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, stock purchases or redemptions); or
- for any transaction from which the director derived an improper personal benefit.

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

- the Registrant is required to indemnify its directors and officers to the fullest extent permitted by the Delaware General Corporation Law, subject to certain very 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 officers in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to certain very 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 amended 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, amended and 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.

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference</u>				<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	
4.1	Form of Common Stock Certificate	S-1/A	333-255754	4.1	5/26/2021	
4.2	Form of Pre-Funded Warrant	8-K	001-40431	4.1	7/30/2024	
4.3	Form of Securities Purchase Agreement	8-K	001-40431	10.1	7/30/2024	
4.4	Form of Registration Rights Agreement	8-K	001-40431	10.2	7/30/2024	
5.1	Opinion of Fenwick & West LLP					X
23.1	Consent of PricewaterhouseCoopers LLP					X
23.2	Consent of Ernst & Young LLP					X
23.3	Consent of Fenwick & West LLP (included in Exhibit 5.1)					X
24.1	Power of Attorney (included on the signature page hereto)					X
107.1	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;
 - (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 Exchange Act 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, 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 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 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.
- (b) The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) 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 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 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

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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 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 Brisbane, State of California, on August 28, 2024.

DAY ONE BIOPHARMACEUTICALS, INC.

By: /s/ Jeremy Bender, Ph.D., M.B.A.
Jeremy Bender, Ph.D., M.B.A.
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Jeremy Bender, Ph.D., M.B.A. and Charles N. York II, and each of them, as his or her 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>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Jeremy Bender, Ph.D., M.B.A.</u> Jeremy Bender, Ph.D., M.B.A.	Chief Executive Officer, President and Director (Principal Executive Officer)	August 28, 2024
<u>/s/ Charles N. York, M.B.A</u> Charles N. York, M.B.A	Chief Operating Officer and Chief Financial Officer (Principal Financial and Accounting Officer)	August 28, 2024
<u>/s/ Garry Nicholson</u> Garry Nicholson	Chair of the Board of Directors	August 28, 2024
<u>/s/ Habib Dable</u> Habib Dable	Director	August 28, 2024
<u>/s/ Scott Garland</u> Scott Garland	Director	August 28, 2024
<u>/s/ Michael Gladstone</u> Michael Gladstone	Director	August 28, 2024

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<u>/s/ William Grossman, M.D., Ph.D.</u> William Grossman, M.D., Ph.D.	Director	August 28, 2024
<u>/s/ Natalie Holles</u> Natalie Holles	Director	August 28, 2024
<u>/s/ John A. Josey, Ph.D., M.B.A.</u> John A. Josey, Ph.D., M.B.A.	Director	August 28, 2024
<u>/s/ Saira Ramasastry, M.S., M.Phil.</u> Saira Ramasastry, M.S., M.Phil.	Director	August 28, 2024



555 California Street
12th Floor
San Francisco, CA 94104

415.875.2300
Fenwick.com

August 28, 2024

Day One Biopharmaceuticals, Inc.
2000 Sierra Point Parkway, Suite 501
Brisbane, CA 94005

Re: Resale Registration Statement on Form S-3ASR

Ladies and Gentlemen:

As counsel to Day One Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), we have examined the Registration Statement on Form S-3ASR filed by the Company with the Securities and Exchange Commission (the "**Commission**") on or about August 28, 2024 (the "**Registration Statement**"), including a related prospectus included in the Registration Statement (the "**Prospectus**"), in connection with the registration for resale under the Securities Act of 1933, as amended (the "**Securities Act**"), of an aggregate of 12,068,959 shares of the Company's common stock, \$0.0001 par value per share (the "**Common Stock**"), which includes 10,551,718 shares of Common Stock (the "**Common Shares**") and 1,517,241 shares of Common Stock (the "**Warrant Shares**" and, together with the Common Shares, the "**Shares**") issuable upon the exercise of pre-funded warrants (the "**Warrants**"), on behalf of the selling stockholders (the "**Selling Stockholders**") identified in the Registration Statement and the prospectus contained within the Registration Statement (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 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 to be sold by the Selling Stockholders pursuant to the Registration Statement and the Prospectus will, when delivered in the manner and for the consideration stated in the Registration Statement and the Prospectus, and, in the case of the Warrant Shares, when issued and sold upon the exercise of the Warrants in accordance with the terms thereof, be validly issued, nonassessable and fully paid.

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 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 Day One Biopharmaceuticals, Inc. of our report dated February 26, 2024 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in Day One Biopharmaceuticals, 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

Dallas, Texas

August 28, 2024

Consent of Ernst & Young LLP

We consent to the reference to our firm under the caption “Experts” in the Registration Statement (Form S-3) and related Prospectuses of Day One Biopharmaceuticals, Inc. for the registration of its common stock and to the incorporation by reference therein of our report dated March 6, 2023, with respect to the consolidated financial statements of Day One Biopharmaceuticals, Inc. incorporated by reference in its Annual Report (Form 10-K) for the year ended December 31, 2023, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

San Mateo, California
August 28, 2024

CALCULATION OF FILING FEE TABLES

Form S-3
(Form Type)Day One Biopharmaceuticals, 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	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Fees to be Paid	Equity ⁽¹⁾	Common stock, par value \$0.0001 per share	Rule 457(a)	12,068,959	\$13.97	\$168,603,357.23	\$0.00014760	\$24,885.86
Fees Previously Paid								
	Total Offering Amounts					\$168,603,357.23		\$24,885.86
	Total Fees Previously Paid							
	Total Fee Offsets							—
	Net Fee Due							\$24,885.86

- (1) Represents the shares of common stock, \$0.0001 par value per share (the “**Common Stock**”), of Day One Biopharmaceuticals, 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 that become issuable in respect of the securities identified in the above table by reason of any stock dividend, stock split, recapitalization or other similar transaction.

Amount of shares registered represents an aggregate of 12,068,959 shares of Common Stock, including 1,517,241 shares of Common Stock issuable upon the exercise of pre-funded warrants of the Registrant.

The proposed maximum offering price per share has been estimated in accordance with Rule 457(c) under the Securities Act solely for the purpose of calculating the registration fee on the basis of \$13.97, the average of the high and low prices of the Common Stock as reported on the Nasdaq Global Select Market on August 23, 2024.