Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to
Commission File No. 001-38944

Akero Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**81-5266573**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

601 Gateway Boulevard, Suite 350
South San Francisco, CA 94080
(650) 487-6488

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	AKRO	The Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 3, 2025, the registrant had 82,316,179 shares of common stock, $0.0001 par value per share, outstanding.

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q. The principal risks and uncertainties affecting our business includes:

- We may not complete the pending transaction with Novo Nordisk A/S, a Danish aktieselskab ("Novo") within the time frame we anticipate or at all, which could have an adverse effect on our business, financial results, and/or operations.
- While the Merger Agreement (as defined below) is in effect, we are subject to restrictions on our business activities, which may prevent us from pursuing strategic business opportunities and taking other actions we may consider advantageous.
- The pendency of the transaction with Novo could adversely affect our business, financial results and/or operations, including by adversely affecting business relationships with employees and third parties and by diverting the attention of management from day-to-day operations.
- In certain instances, the Merger Agreement requires us to pay a termination fee to Novo, which could require us to use available cash that would have otherwise been available for general corporate purposes.
- We have incurred, and will continue to incur, direct and indirect costs as a result of the pending transaction with Novo.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with metabolic dysfunction-associated steatohepatitis ("MASH," formerly known as nonalcoholic steatohepatitis), significant competition for recruiting such patients in clinical trials, and restrictions on patients and investigators related to outbreaks of infectious diseases or public health crises.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.
- Failures or delays in the commencement or completion of, or ambiguous or negative results from our planned clinical trials of our product candidates could result in increased costs to us and could delay, prevent, or limit our ability to generate revenue and continue our business.
- Clinical development is uncertain and our clinical trials for efruxifermin ("EFX") and any future product candidates may experience delays, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.
- We rely and will continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.
- The manufacture of our product candidates is complex and we may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.
- We are heavily dependent on the success of EFX, our only product candidate.
- If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed and our business will be more vulnerable to any problems that we encounter in developing and commercializing our product candidate.
- We may develop EFX, and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.
- If we are not successful in discovering, developing, receiving regulatory approval for and commercializing EFX and any future product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

- We may be required to make significant payments under our license agreement for EFX.
- The regulatory approval processes of the U.S. Food and Drug Administration (the "FDA") and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for EFX or any future product candidate would substantially harm our business.
- Even if we are able to obtain regulatory approvals for our product candidate or any future product candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.
- Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.
- We have incurred significant losses since our inception and we expect to incur losses for the foreseeable future.
- We currently have a limited operating history, have not generated any revenue to date, and may never become profitable.
- We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of our product candidate or develop any future product candidates.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements involve risks, uncertainties, and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- the proposed Merger (as defined below) with Novo;
- the success, cost and timing of our product development activities and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to successfully enroll, conduct and complete the three parallel, randomized, placebo-controlled, global clinical trials of our Phase 3 SYNCHRONY program, including our ability to reach agreement with the FDA and other regulatory authorities on clinical trial designs
- the impact of geopolitical tensions, such as the increasing conflict in the Middle East, including between India and Pakistan, on clinical trial sites, such as those in India, Israel and Turkey where clinical sites have been activated to participate in our Phase 3 SYNCHRONY program;
- our ability to maintain our expected timeline for reporting primary endpoint results of the Phase 3 program called SYNCHRONY, which is comprised of three ongoing clinical trials (*Outcomes, Histology, and Real-World*);
- the potential for another pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, to disrupt our business plans, product development activities, ongoing clinical trials, including the timing and enrollment of patients, the health of our employees and the strength of our supply chain;
- our ability to advance any product candidate into or successfully complete any clinical trial;
- our ability to successfully manufacture our product candidates for future clinical trials or for commercial use, if approved;
- the potential for our identified research priorities to advance our technologies;
- our ability to obtain and, if obtained, maintain regulatory approval of EFX or any future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- the ability to license additional intellectual property relating to any future product candidates and to comply with our existing license agreement;
- our ability to commercialize our products in light of the intellectual property rights of others;
- the success of competing therapies that are or become available;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to attract and retain key scientific or management personnel;

- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the impact of unstable global economic and geopolitical conditions, including trade restrictions such as sanctions, tariffs, reciprocal and retaliatory tariffs, and other tariff-related measures; regulatory requirements, legal actions, or enforcement; and inflation rates on our business, financial condition and results of operation;
- the impact of laws and regulations; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or into which we may enter.

You should read this Quarterly Report on Form 10-Q and the documents that we reference herein and have filed or incorporated by reference as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

NOTE REGARDING TRADEMARKS

Akero Therapeutics, Inc. is the owner of the AKERO trademark, as well as certain other trademarks, including design versions of some of these trademarks. The symbols ™ and ® are not used in connection with the presentation of these trademarks in this report and their absence does not indicate a lack of trademark rights. Certain other trademarks used in this report are the property of third-party trademark owners and may be presented with or without trademark references.

All brand names or trademarks appearing in this report are the property of their respective owners. Unless the context requires otherwise, references in this report to "Akero," the "Company," "we," "us," and "our" refer to Akero Therapeutics, Inc. and its subsidiary.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Akero Therapeutics, Inc.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	September 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 176,032	$ 340,238
Short-term marketable securities	561,794	402,840
Prepaid expenses and other current assets	16,709	27,302
Total current assets	754,535	770,380
Long-term marketable securities	250,490	54,751
Right of use asset	552	755
Total assets	$ 1,005,577	$ 825,886
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 20,399	$ 9,027
Accrued expenses and other current liabilities	27,252	30,727
Total current liabilities	47,651	39,754
Loan payable, noncurrent	—	35,297
Warrant liability	—	194
Operating lease liability, noncurrent	289	529
Total liabilities	47,940	75,774
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.0001 par value, 150,000,000 shares authorized as of September 30, 2025 and December 31, 2024; 80,149,218 and 72,383,013 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	8	7
Additional paid-in capital	2,004,755	1,575,313
Accumulated other comprehensive income	1,826	948
Accumulated deficit	(1,048,952)	(826,156)
Total stockholders' equity	957,637	750,112
Total liabilities and stockholders' equity	$ 1,005,577	$ 825,886

The accompanying notes are an integral part of these condensed consolidated financial statements.

Akero Therapeutics, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 78,883	$ 72,232	$ 217,704	$ 178,204
General and administrative	11,353	9,471	34,287	29,194
Total operating expenses	90,236	81,703	251,991	207,398
Loss from operations	(90,236)	(81,703)	(251,991)	(207,398)
Interest expense	(1,092)	(1,246)	(3,418)	(3,468)
Loss on Extinguishment of Loan Payable	(1,557)	—	(1,557)	—
Interest and other income, net	11,319	10,244	34,170	28,830
Net loss	(81,566)	(72,705)	(222,796)	(182,036)
Net unrealized gain on marketable securities	838	2,364	878	1,833
Comprehensive loss	$ (80,728)	$ (70,341)	$ (221,918)	$ (180,203)
Net loss per common share, basic and diluted	$ (0.99)	$ (1.05)	$ (2.76)	$ (2.76)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	82,008,267	69,442,136	80,807,705	65,982,798

The accompanying notes are an integral part of these condensed consolidated financial statements.

Akero Therapeutics, Inc.

Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In-Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balances at December 31, 2023	55,754,445	$ 6	$ 1,109,126	$ 270	$ (574,096)	$ 535,306
Exercise of stock options	233,321	—	1,769	—	—	1,769
Common stock issued for vested restricted stock units	10,663	—	—	—	—	—
Vested warrants issued pursuant to loan agreement	—	—	431	—	—	431
Issuance of common stock pursuant to At-The-Market ("ATM") offering, net of issuance costs	500,000	—	10,604	—	—	10,604
Issuance of common stock pursuant to a follow-on offering, net of issuance costs	12,650,000	1	344,437	—	—	344,438
Stock-based compensation expense	—	—	7,398	—	—	7,398
Net unrealized loss on marketable securities	—	—	—	(349)	—	(349)
Net loss	—	—	—	—	(53,344)	(53,344)
Balances at March 31, 2024	69,148,429	7	1,473,765	(79)	(627,440)	846,253
Exercise of stock options	334	—	3	—	—	3
Common stock issued for vested restricted stock units	40,661	—	—	—	—	—
Issuance of common stock pursuant to ESPP purchases	16,244	—	324	—	—	324
Stock-based compensation expense	—	—	7,656	—	—	7,656
Net unrealized loss on marketable securities	—	—	—	(182)	—	(182)
Net loss	—	—	—	—	(55,987)	(55,987)
Balances at June 30, 2024	69,205,668	7	1,481,748	(261)	(683,427)	798,067
Exercise of stock options	367,615	—	3,131	—	—	3,131
Common stock issued for vested restricted stock units	41,304	—	—	—	—	—
Stock-based compensation expense	—	—	7,468	—	—	7,468
Net unrealized gain on marketable securities	—	—	—	2,364	—	2,364
Net loss	—	—	—	—	(72,705)	(72,705)
Balances at September 30, 2024	69,614,587	$ 7	$ 1,492,347	$ 2,103	$ (756,132)	$ 738,325
Balances at December 31, 2024	72,383,013	$ 7	$ 1,575,313	$ 948	$ (826,156)	$ 750,112
Exercise of stock options	438,460	—	7,396	—	—	7,396
Common stock issued for vested restricted stock units	40,789	—	—	—	—	—
Issuance of common stock and accompanying pre-funded warrants in a follow-on offering, net of issuance costs	6,427,170	1	377,780	—	—	377,781
Issuance of common stock pursuant to ATM offering, net of issuance costs	380,488	—	10,361	—	—	10,361
Stock-based compensation expense	—	—	8,784	—	—	8,784
Net unrealized gain on marketable securities	—	—	—	137	—	137
Net loss	—	—	—	—	(70,725)	(70,725)
Balances at March 31, 2025	79,669,920	8	1,979,634	1,085	(896,881)	1,083,846
Exercise of stock options	160,301	—	3,062	—	—	3,062
Common stock issued for vested restricted stock units	69,787	—	—	—	—	—
Issuance of common stock pursuant to ESPP purchases	19,195	—	458	—	—	458
Stock-based compensation expense	—	—	9,055	—	—	9,055
Net unrealized (loss) on marketable securities	—	—	—	(97)		(97)
Net loss	—	—	—	—	(70,505)	(70,505)
Balances at June 30, 2025	79,919,203	8	1,992,209	988	(967,386)	1,025,819

Akero Therapeutics, Inc.

Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) (continued)
(In thousands, except share amounts)
(Unaudited)

Exercise of stock options	177,573	—	3,285	—	—	3,285
Common stock issued for vested restricted stock units	52,442	—	—	—	—	—
Stock-based compensation expense	—	—	9,261	—	—	9,261
Net unrealized gain on marketable securities	—	—	—	838	—	838
Net loss	—	—	—	—	(81,566)	(81,566)
Balances at September 30, 2025	80,149,218	$ 8	$ 2,004,755	$ 1,826	$ (1,048,952)	$ 957,637

The accompanying notes are an integral part of these condensed consolidated financial statements.

Akero Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (222,796)	$ (182,036)
Adjustments to reconcile net loss to net cash used in operating activities:		.
Stock-based compensation expense	27,100	22,522
Depreciation	—	3
Non-cash lease expense	203	188
Net amortization of premiums and discounts on marketable securities	(7,752)	(10,106)
Amortization of debt issuance costs and discount	543	433
Loss on extinguishment of loan payable	1,557	—
Fair value change in warrant liability	(194)	526
Unrealized foreign exchange gain and loss	—	67
Acquired in-process research and development expense	—	999
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	10,593	(19,495)
Accounts payable	11,379	18,118
Accrued expenses and other current liabilities	(3,500)	5,955
Operating lease liability	(214)	(191)
Net cash (used in) operating activities	(183,081)	(163,017)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of short-term and long-term marketable securities	(732,473)	(436,316)
Proceeds from maturities of short-term marketable securities	386,411	312,335
Purchase of in-process research and development	—	(999)
Net cash (used in) investing activities	(346,062)	(124,980)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from the exercise of stock options	13,742	4,903
Proceeds from the issuance of common stock pursuant to employee stock purchase plan purchases	458	324
Proceeds from the issuance of common stock and pre-funded warrants in a follow-on public offering	378,350	—
Proceeds from the issuance of common stock in a follow-on public offering	—	344,839
Proceeds from the issuance of common stock pursuant to the ATM offering	10,361	10,604
Proceeds from loan payable	—	10,000
Repayment of loan payable	(37,398)	—
Payment of debt and equity issuance costs	(576)	(815)
Net cash provided by financing activities	364,937	369,855
Net (decrease) increase in cash and cash equivalents	(164,206)	81,858
Cash and cash equivalents at the beginning of the period	340,238	234,207
Cash and cash equivalents at the end of the period	$ 176,032	$ 316,065
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 3,216	$ 2,948
NON-CASH INVESTING AND FINANCING INFORMATION:		
Change in net unrealizable gain on marketable securities	$ 878	$ 1,833
Warrant liability costs reclassified to additional paid-in equity on vested warrants issued	$ —	$ 431
Debt and equity issuance costs included in accounts payable and accrued expenses and other current liabilities	$ —	$ 15

The accompanying notes are an integral part of these condensed consolidated financial statements.

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

1. Nature of the business and basis of presentation

Akero Therapeutics, Inc., together with its wholly owned subsidiary Akero Securities Corporation ("Akero" or the "Company"), is a clinical-stage company dedicated to developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, including metabolic dysfunction-associated steatohepatitis, or MASH, formerly known as non-alcoholic steatohepatitis, or NASH. MASH is a severe form of metabolic dysfunction-associated steatotic liver disease, or MASLD, formerly known as nonalcoholic fatty liver disease, or NAFLD, characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, cancer and death. The Company's lead product candidate, efruxifermin, or EFX, is an analog of fibroblast growth factor 21, or FGF21, which is an endogenously expressed hormone that protects against cellular stress and regulates metabolism of lipids, carbohydrates and proteins throughout the body. The Company has an ongoing, global Phase 3 program called SYNCHRONY, which is comprised of three clinical trials (*Outcomes*, *Histology*, and *Real-World*) with an expected total enrollment of about 3,500 patients, which is designed to support applications for marketing approval for patients with pre-cirrhotic MASH (F2-F3) and compensated cirrhosis (F4) due to MASH. The SYNCHRONY program builds on two biopsy-based Phase 2b trials in corresponding patient populations, with a combined total of over 300 patients treated for up to 96 weeks. Based on statistically significant fibrosis regression and MASH resolution among patients with either biopsy-confirmed pre-cirrhotic MASH (F2-F3) or compensated cirrhosis (F4) due to MASH, the Company believes EFX has the potential, if approved, to be an important medicine for treating MASH.

The Company is subject to risks and uncertainties common to mid-stage companies in the biotechnology industry, including, but not limited to, completion and success of clinical testing, preparation for a potential commercial launch of EFX, if approved, development by competitors of new technological innovations, compliance with governmental regulations, dependence on key personnel and protection of proprietary technology and the ability to secure additional capital to fund operations. EFX will require extensive clinical testing prior to regulatory approval and commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Agreement and Plan of Merger

On October 9, 2025, the Company announced it entered into an Agreement and Plan of Merger (the "Merger Agreement") with Novo and NN Invest Sub, Inc, a Delaware corporation and a direct or indirect wholly owned subsidiary of Novo ("Merger Sub"), providing for the merger of Merger Sub with and into the Company (the "Merger"), with the Company surviving the Merger as a wholly owned subsidiary of Novo (see Note 14).

Basis of presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company after elimination of all intercompany accounts and transactions. All adjustments necessary for the fair presentation of the Company's condensed consolidated financial statements for the periods presented have been reflected.

Liquidity

In accordance with Accounting Standards Update ("ASU") No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued.

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

Since its initial public offering ("IPO") in June 2019, the Company has raised capital primarily through the sale of its common stock in follow-on public offerings, registered direct offerings and At-the-Market ("ATM") offerings. The Company has incurred recurring losses since its inception, including net losses of $222,796 and $182,036 for the nine months ended September 30, 2025 and 2024, respectively, and net losses of $252,060 and $151,759 for the years ended December 31, 2024 and 2023, respectively. In addition, as of September 30, 2025, the Company had an accumulated deficit of $1,048,952. The Company expects to continue to generate operating losses for the foreseeable future. As of November 7, 2025, the issuance date of these condensed consolidated financial statements, the Company expects that its existing cash, cash equivalents, short-term and long-term marketable securities of $988,316 as of September 30, 2025, will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these condensed consolidated financial statements. If the Merger is not consummated, the Company expects that it will require additional funding to complete the clinical development of EFX, commercialize EFX, if it receives regulatory approval, and pursue in-licenses or acquisitions of other product candidates.

If the Merger is not consummated and the Company is unable to obtain additional funding, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

2. Summary of significant accounting policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements and the notes thereto in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on February 28, 2025. Except as reflected below, there were no changes to the Company's significant accounting policies as described in the Annual Report on Form 10-K. Reflected in this note are updates to accounting policies, including the impact of the adoption of new policies.

Unaudited interim financial statements

The accompanying unaudited condensed consolidated financial statements have been prepared by the Company in accordance with GAAP for interim financial reporting and as required by Regulation S-X, Rule 10-01. The unaudited condensed consolidated financial statements have been prepared on the same basis as the Company's audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to fairly state the Company's financial position and the results of its operations and cash flows. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2025 and 2024 are unaudited. The results for the three and nine months ended September 30, 2025 are not necessarily indicative of results to be expected for the year ending December 31, 2025, any other interim periods, or any future year or period.

Use of estimates

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the condensed consolidated financial statements and accompanying notes. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the recognition of research and development expenses, stock-based compensation expense, warrant liabilities and the valuation allowance for deferred tax assets. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates when there

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, short-term and long-term marketable securities. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash investments in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. At September 30, 2025, all of the Company's cash, cash equivalents, short-term and long-term investments were held at three accredited financial institutions.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. Under ASU No. 2023-09, entities are required to uniformly classify and present greater disaggregation of information in the rate reconciliation and income taxes paid. ASU No. 2023-09 is intended to benefit investors by improving the transparency and decision usefulness of income tax disclosures. The new standard is effective for annual periods beginning after December 15, 2024. The Company adopted the ASU No. 2023-09 effective January 1, 2025. The adoption of this guidance did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

Recently Issued Accounting Standards Not Yet Adopted

In November 2024 and January 2025, the FASB issued ASU No. 2024-03 and ASU No. 2025-01, *Comprehensive Income - Expense Disaggregation Disclosures*, which will improve the disclosures about a public business entity's expenses and address requests from investors for more detailed information about the types of expenses in commonly presented expense captions such as cost of sales, selling, general and administrative, and research and development. The amendments are effective for fiscal years beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted for annual financial statements that have not yet been issued or made available. The amendments should be applied on either (1) prospectively to financial statements issued for reporting periods after the effective date or (2) retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating the provisions of the amendments and the effect on its future condensed consolidated financial statements.

3. Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The following is a summary of the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2025 and December 31, 2024:

	September 30, 2025			
	Total	Level 1	Level 2	Level 3
Money market funds	$ 140,729	$ 140,729	—	—
U.S. Treasury securities	545,474	545,474	—	—
U.S. Government agency securities	54,774	—	54,774	—
Commercial paper	29,969	—	29,969	—
Corporate debt securities	202,033	—	202,033	—
Total assets	$ 972,979	$ 686,203	$ 286,776	$ —

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
Money market funds	$ 314,092	$ 314,092	$ —	$ —
U.S. Treasury securities	248,885	248,885	—	—
U.S. Government agency securities	60,691	—	60,691	—
Commercial paper	34,544	—	34,544	—
Corporate debt securities	113,471	—	113,471	—
Total assets	$ 771,683	$ 562,977	$ 208,706	$ —
Warrant liabilities	$ 194	$ —	$ —	$ 194
Total liabilities	$ 194	$ —	$ —	$ 194

Level 2 assets were valued by the Company using quoted prices in active markets for similar securities.

The carrying values of the Company's prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. During the nine months ended September 30, 2025 and the twelve months ended December 31, 2024, there were no transfers between Level 1, Level 2 and Level 3.

The value of the Loan Payable approximated its fair value as of December 31, 2024 and was classified as a Level 3 liability as of that date. The Company estimated the fair value of the warrant liabilities as of December 31, 2024 using the Black-Scholes model based on key assumption and inputs (see Note 6). The Company utilized a probability assessment to estimate the likelihood of vesting for the remaining Loan Agreement warrants and allocated the probability of occurrence percentage to the fair value calculated.

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

4. Short and long-term marketable securities

The following is a summary of short-term and long-term marketable securities as of September 30, 2025 and December 31, 2024:

	September 30, 2025				
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Credit losses	Fair value
Money market funds	$ 140,729	—	—	$ —	$ 140,729
U.S. Treasury securities	544,143	1,342	(12)	—	545,473
U.S. Government agency securities	54,748	27	—	—	54,775
Commercial paper	29,969	1	—	—	29,970
Corporate debt securities	201,564	468	—	—	202,032
Total	$ 971,153	$ 1,838	$ (12)	$ —	$ 972,979

Cash equivalents	$ 160,695
Short-term marketable securities	561,794
Long-term marketable securities	250,490
Total	$ 972,979

	December 31, 2024				
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Credit losses	Fair value
Money market funds	$ 314,092	$ —	$ —	$ —	$ 314,092
U.S. Treasury securities	248,202	738	(55)	—	248,885
U.S. Government agency securities	60,596	95	—	—	60,691
Commercial paper	34,500	45	(1)	—	34,544
Corporate debt securities	113,346	141	(16)	—	113,471
Total	$ 770,736	$ 1,019	$ (72)	$ —	$ 771,683

Cash equivalents	$ 314,092
Short-term marketable securities	402,840
Long-term marketable securities	54,751
Total	$ 771,683

The following table presents the contractual maturities of the Company's short-term and long-term marketable securities as of September 30, 2025 and December 31, 2024.

	September 30, 2025	December 31, 2024
Due within one year	$ 561,794	$ 402,840
Due after one year through two years	250,490	54,751
Total	$ 812,284	$ 457,591

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

5. Accrued expenses and other current liabilities

The following is a summary of accrued expenses and other current liabilities as of September 30, 2025 and December 31, 2024:

	September 30, 2025	December 31, 2024
Accrued external research and development expenses	$ 21,401	$ 28,925
Accrued employee compensation and benefits	4,976	1,171
Short-term lease liability and other	875	631
Total	$ 27,252	$ 30,727

6. Loan Payable and Warrant Liability

On June 15, 2022, the Company entered into the Loan Agreement with Hercules Capital, Inc. ("Hercules"), which was subsequently amended on June 7, 2023 and February 28, 2024, for an aggregate principal amount of $150,000 ("Term Loan"). Pursuant to the amended Loan Agreement, the Term Loan was available to the Company in five tranches, subject to certain terms and conditions.

Under the terms of the Loan Agreement, the Company received $10,000 upon closing, $15,000 was borrowed in March 2023 and an additional $10,000 was borrowed in connection with the second amendment on February 28, 2024 (the "Tranche I and Tranche II Commitments"). On September 23, 2025, the Company terminated the Term Loan and repaid the total $35,000 borrowings. The Company recorded a Loss on Extinguishment of Note Payable of $1,557 in connection with the repayment.

The Loan Agreement required the Company to issue warrants to Hercules to purchase shares of the Company's common stock, par value $0.0001 per share ("common stock"). Warrants to purchase a total of 64,257 shares of common stock were issued to Hercules in connection with the borrowings under the Term Loan, which remain outstanding as of September 30, 2025 (see Note 7). The Company is not obligated to issue any additional warrants to Hercules.

7. Stockholder's equity (deficit)

Common stock

As of September 30, 2025 and December 31, 2024, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 150,000,000 shares of $0.0001 par value common stock. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. The holders of common stock, voting exclusively and as a separate class, have the exclusive right to vote for the election of directors of the Company. Common stockholders are entitled to receive dividends, as may be declared by the board of directors. Through September 30, 2025, no cash dividends had been declared or paid.

In March 2023, the Company entered into a sales agreement with Jefferies LLC (the "Sales Agreement") activating an At-The-Market ("ATM") facility. Pursuant to the Sales Agreement, the Company filed a prospectus supplement on March 17, 2023, under which the Company may offer and sell shares of common stock, having an aggregate value of up to $200,000. In April and May 2023, the Company sold 3,006,052 shares of common stock under the Sales Agreement, at an average price of $42.38 per share, and received net proceeds of $123,824, after deducting sales agent commissions and issuance costs of approximately $3,578. In February 2024, the Company sold an additional

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

500,000 shares of common stock under the Sales Agreement, at an average price of $21.75 per share, and received net proceeds of $10,604, after deducting sales agent commissions and issuance costs of approximately $271.

On May 16, 2023, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Jefferies LLC, ("Jefferies"), as a representative of the several underwriters, pursuant to which the Company agreed to issue and sell 5,238,500 shares of the Company's common stock at $42.00 per share in a registered direct offering pursuant to the Company's effective shelf registration statement on Form S-3ASR and a related prospectus supplement filed with the SEC. The offering closed on May 16, 2023. The Company received net proceeds of $210,956, after deducting underwriters commissions and offering costs incurred by the Company of approximately $9,061.

On March 8, 2024, the Company completed a follow-on public offering at which time the Company issued 12,650,000 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 1,650,000 additional shares of common stock, at a public offering price of $29.00 per share. The Company received $344,838 net of underwriting discounts and commissions of $22,011, but before deducting offering costs incurred by the Company of approximately $401.

On May 10, 2024, the Company entered into an amendment to the Sales Agreement ("Amended Sales Agreement") to increase the aggregate offering price of the shares of the Company's common stock by an additional $200,000. In accordance with the terms of the Amended Sales Agreement, the Company may now offer and sell shares of its common stock having an aggregate offering price of up to $261,723 from time to time.

In November and December 2024, the Company sold 2,249,907 shares of common stock under the Amended Sales Agreement, at an average price of $30.83 per share, and received gross proceeds of $69,373 before deducting sales agent commissions and issuance costs of approximately $1,734. In January 2025, the Company sold an additional 380,488 shares of common stock under the Amended Sales Agreement, at an average price of $27.93 for gross proceeds of $10,627 and before deducting sales agent commissions of approximately $266.

In January 2025, the Company sold 6,427,170 shares of the its common stock at a public offering price of $48.00 per share, and in lieu of common stock to certain investors, pre-funded warrants to purchase 1,958,247 shares of common stock at a public offering price of $47.9999 per pre-funded warrant, which represents the per share public offering price of each share of common stock less the $0.0001 per share exercise price for each pre-funded warrant. The pre-funded warrants do not have an expiration date and are exercisable at any time. The pre-funded warrants are classified within stockholders' equity on the Company's condensed consolidated balance sheet as of September 30, 2025. The Company received net proceeds of $378,350, after deducting underwriting discounts and commission of $24,150, but before deducting offering costs incurred by the Company of approximately $569. The Company may receive nominal proceeds, if any, from the exercise of the prefunded warrants. There were no pre-funded warrants exercised during the nine months ended September 30, 2025.

As of September 30, 2025 and December 31, 2024, there were 80,149,218 and 72,383,013 shares of common stock issued and outstanding, respectively.

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

The following shares of common stock were reserved for issuance as follows:

	September 30, 2025	December 31, 2024
Options outstanding under the 2018 Stock Option and Grant Plan	387,036	577,089
Options outstanding under the 2019 Stock Option and Incentive Plan	6,963,148	6,983,360
Unvested restricted stock units outstanding under the 2019 Stock Option and Incentive Plan	725,304	715,306
Warrants to purchase common stock associated with Loan Agreement	64,257	64,257
Pre-funded warrants sold in a public offering in January 2025	1,958,247	—
Options available for future grant	4,094,979	1,938,688
Warrants available for future grant to Hercules	—	211,137
Common stock available for ATM program	9,092,586	9,473,074
2019 Employee Stock Purchase Plan	2,365,270	1,973,662
Total	25,650,827	21,936,573

Undesignated preferred stock

The Company's fourth amended and restated certificate of incorporation authorizes the Company to issue up to 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share. There were no undesignated preferred shares issued or outstanding as of September 30, 2025.

Warrants Associated with Loan Agreement

In connection with the Loan Agreement with Hercules (see Note 6), the Company was obligated to issue warrants to purchase shares of the Company's common stock. Warrants to purchase a total of 64,257 shares of common stock were issued to Hercules in connection with the borrowings under the Term Loan, which remain outstanding as of September 30, 2025. The Company recorded the warrants at their relative fair value of $227 as of the date of issuance in the shareholders equity category of the balance sheet. The Company is not obligated to issue any additional warrants to Hercules.

8. Stock-based awards

2019 Stock option and incentive plan

The 2019 Plan was adopted and approved by the Company's board of directors in May 2019 and by the Company's stockholders in June 2019. The 2019 Plan became effective on June 18, 2019 and replaced the Company's 2018 Stock Option and Grant Plan on that date. The 2019 Plan allows the board of directors or the compensation committee of the board of directors to make equity-based incentive awards to the Company's officers, employees, directors or other key persons (including consultants). The number of shares initially reserved for issuance under the 2019 Plan was 2,572,457, which included the 107,635 shares transferred from the 2018 Plan, and shall be cumulatively increased on each January 1 by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's board of directors or compensation committee of the board of directors. The 2019 Plan was increased by 2,230,177 shares on January 1, 2024 and by 2,895,320 shares on January 1, 2025.

The 2019 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

may not be greater than ten years. All incentive options granted to any person possessing more than 10% of the total combined voting power of all classes of shares may not have an exercise price of less than 110% of the fair market value of the common stock on the grant date. Stock options granted to employees, officers, members of the board of directors and consultants will typically vest over a four-year period.

Shares that are expired, terminated, surrendered or canceled under the 2019 Plan without having been fully exercised will be available for future awards.

2019 Employee stock purchase plan

The 2019 Employee Stock Purchase Plan (the "2019 ESPP") was adopted and approved by the Company's board of directors in May 2019 and by the Company's stockholders in June 2019. The 2019 ESPP became effective on June 18, 2019, at which time 273,869 shares were reserved for issuance. The 2019 ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2020 and each January 1 through January 1, 2029, by the least of (i) 1% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31, (ii) 410,803 shares or (iii) such number of shares as determined by the compensation committee. The 2019 ESPP was increased by 410,803 shares on January 1, 2024 and by 410,803 shares on January 1, 2025.

Stock option valuation

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees, directors and consultants as follows, presented on a weighted average basis:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Expected term (in years)	6.00	5.96	5.98	5.93
Expected volatility	92.24 %	88.06 %	90.02 %	86.38 %
Risk-free interest rate	3.91 %	4.41 %	4.26 %	4.30 %
Expected dividend yield	0.00 %	0.00 %	0.00 %	0.00 %

Stock options

The following table summarizes the Company's stock option activity since December 31, 2024:

	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (000's)
Balance outstanding, December 31, 2024	7,560,449	$ 24.38	7.53	$ 46,487
Options granted	599,525	$ 33.82		
Options exercised	(776,334)	$ 17.70		
Options cancelled	(33,456)	$ 38.33		
Balance outstanding, September 30, 2025	7,350,184	$ 25.79	7.13	$ 160,294
Vested and expected to vest, September 30, 2025	7,350,184	$ 25.79	7.13	$ 160,294
Exercisable, September 30, 2025	4,668,824	$ 24.43	6.30	$ 108,182

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

The weighted average grant-date fair value per share of stock options granted during the three months ended September 30, 2025 and 2024 was $37.60 and $17.56, respectively. Additionally, the weighted average grant-date fair value per share of stock options granted during the nine months ended September 30, 2025 and 2024 was $25.80 and $16.54, respectively.

Restricted Stock Units

The 2019 Plan allows for the grants of Restricted Stock Units ("RSUs"). Generally, the RSUs are subject to a four-year vesting period, vesting in equal quarterly or semi-annual installments over the vesting period.

The following table summarizes the Company's RSUs activity since December 31, 2024:

	Underlying Shares	Weighted-Average Grant Date Fair Value per Share	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (000's)
Balance outstanding, December 31, 2024	715,306	$ 27.04	1.74	$ 19,900
Granted	178,211	$ 39.27		
Vested	(163,018)	$ 28.23		
Cancelled or forfeited	(5,195)	$ 24.95		
Balance outstanding, September 30, 2025	725,304	$ 29.79	1.35	$ 34,437

The aggregate intrinsic value of RSUs is calculated based of the fair value of the Company's common stock and the outstanding RSUs.

The weighted average grant-date fair value per share of RSUs granted during the three months ended September 30, 2025 and 2024 was $51.41 and $23.16, respectively. Additionally, the weighted average grant-date fair value per share of RSUs granted during the nine months ended September 30, 2025 and 2024 was $39.27 and $23.46, respectively.

Stock-based compensation

The following table summarizes the Company's stock-based compensation expense during the three and nine months ended September 30, 2025 and 2024:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Classified within research and development expense	$ 3,732	$ 2,903	$ 10,879	$ 8,487
Classified within general and administrative expense	5,529	4,565	16,221	14,035
Total	$ 9,261	$ 7,468	$ 27,100	$ 22,522

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

As of September 30, 2025, total unrecognized compensation cost related to unvested stock options and RSUs was $53,075 and $18,880, respectively. Compensation cost for these unvested stock options and RSUs is expected to be recognized over a weighted average period of 2.46 years and 2.45 years, respectively.

9. Amgen license agreement

In June 2018, the Company entered into a license agreement (the "Amgen Agreement") with Amgen, Inc. ("Amgen") pursuant to which the Company was granted an exclusive license to certain patents and intellectual property related to a long-acting FGF21 analog in order to commercially develop, manufacture, use and distribute FGF21 as a treatment for MASH and other serious metabolic diseases. The Amgen Agreement provides the Company with exclusive global rights to the licensed products and the right to grant sublicenses that cover EFX to third parties.

In exchange for these rights, the Company made an upfront payment of $5,000 and issued 2,653,333 shares of Series A Preferred Stock with a fair value of $1,353 to Amgen. Amgen was also entitled to maintain a 10% ownership interest of the outstanding shares of the Company's common stock, on a fully diluted and converted basis, through the second closing of the Company's Series A Preferred Stock financing. In November 2018, in connection with the second closing of the Company's Series A Preferred Stock financing, the Company issued 3,205,128 shares of Series A Preferred Stock to Amgen for a total value of $7,404, satisfying its anti-dilution obligation under the Amgen Agreement.

Under the Amgen Agreement, the Company made a milestone payment in the third quarter of 2019 of $2,500 in connection with dosing the first patient in the BALANCED study, a second milestone payment of $7,500 was paid in December 2023 with dosing the first patient in our Phase 3 SYNCHRONY program, and is obligated to pay Amgen up to $30,000 in connection with marketing approvals, and aggregate milestone payments of up to $75,000 upon the achievement of specified commercial milestones for all products licensed under the Amgen Agreement.

Under the Amgen Agreement, the Company is obligated to pay Amgen tiered royalties ranging from a low to high single-digit percentages on annual net sales of the licensed products, beginning on the first commercial sale of such licensed products in each country and expiring on a country-by-country basis on the latest of (i) the expiration of the last valid patent claim covering such licensed products in such country, (ii) the loss of regulatory exclusivity in such country, and (iii) ten years after the first commercial sale of such licensed product in such country. The royalty payments are subject to reduction under specified conditions set forth in the Amgen Agreement.

The Company is solely responsible for all development, manufacturing, and commercial activities and costs of the licensed products, including clinical studies or other tests necessary to support the use of a licensed product. The Company is also responsible for costs related to the filing, prosecution and maintenance of the licensed patent rights.

The Amgen Agreement will remain in effect until the expiration of the royalty term in all countries for all licensed products. The Amgen Agreement may be terminated by either party with at least 90 days' notice in the event of material breach by the other party that remains uncured for 90 days, by either party for insolvency or bankruptcy of the other party and immediately by Amgen if the Company challenges the licensed patents. The Company may also terminate the Amgen Agreement with 90 days' written notice for discretionary reasons such as scientific, technical, regulatory or commercial issues, as defined in the Amgen Agreement.

During the three and nine months ended September 30, 2025 and 2024, the Company did not record any research and development expense under the Amgen Agreement.

10. Income taxes

During the three and nine months ended September 30, 2025 and 2024, the Company did not record any income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each period

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

due to its uncertainty of realizing a benefit from those items. All of the Company's operating losses since inception have been generated in the United States.

On August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. The IRA includes implementation of a new alternative minimum tax, an excise tax on stock buybacks, and significant tax incentives for energy and climate initiatives, among other provisions. The Company is evaluating the provisions included under the IRA and does not expect the provisions to have a material impact to the Company's condensed consolidated financial statements.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law. The OBBBA introduces significant changes to U.S. income tax legislation, including the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework, and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with some provisions taking effect in 2025 and others being implemented through 2027. The Company is currently evaluating the impact of the OBBBA on its financial statements and will continue to evaluate the full impact of these legislative changes as additional guidance becomes available; however, it does not anticipate any material change to its estimated annual effective tax rate in 2025.

11. Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Numerator - Net loss	$ (81,566)	$ (72,705)	$ (222,796)	$ (182,036)
Denominator - Weighted average common shares outstanding, basic and diluted	82,008,267	69,442,136	80,807,705	65,982,798
Net loss per share, basic and diluted	$ (0.99)	$ (1.05)	$ $ (2.76)	$ (2.76)

The 1,958,247 pre-funded warrants issued in January 2025 and outstanding as of September 30, 2025 (see Note 7) were included in computing the weighted average common shares outstanding used in calculating basic and diluted net loss per share.

The Company's potentially dilutive securities, which include stock options, warrants and unvested restricted stock units, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Three and Nine Months Ended September 30,	
	2025	2024
Options to purchase common stock	7,350,184	7,296,394
Unvested restricted stock units	725,304	536,717
Warrants to purchase common stock issued to Hercules	64,257	64,257
Warrants available for future grant to Hercules	—	211,137
Total	8,139,745	8,108,505

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

12. Commitments and contingencies

Operating lease

In February 2020, the Company entered into a seven-year agreement to occupy 6,647 square feet of office space in South San Francisco, California. The lease commenced on July 10, 2020 when the Company took occupancy of the leased space and the lease was determined to be operating classified. Under the agreement, the Company is required to make approximately $2,300 in total minimum payments during the term. The Company is also required to pay its proportionate share of building operating and tax costs after the first year under lease which are not included in the measurement of the lease and treated as variable lease cost and expensed when incurred.

As of September 30, 2025, maturities of the Company's operating lease liability was as follows:

2025	$	87
2026		351
2027		208
Total future minimum lease payments		646
Less imputed interest		(41)
Present value of operating lease liabilities	$	605

As of September 30, 2025, the total lease liability was $605, of which $289 was noncurrent and $316 was short-term and classified within "Accrued expenses and other current liabilities" on the condensed consolidated balance sheet.

Research and manufacturing and other commitments

The Company has entered into agreements with contract research organizations and contract manufacturing organizations to provide services in connection with its nonclinical studies and clinical trials and to manufacture clinical development materials. As of September 30, 2025, the Company had non-cancelable purchase and other commitments under these agreements totaling $90,670.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of September 30, 2025.

Legal proceedings

The Company does not have contingency reserves established for any litigation liabilities. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses costs related to such legal proceedings as they are incurred.

On April 26, 2024, a purported stockholder of the Company filed a lawsuit, captioned Klobus v. Akero Therapeutics, Inc., No. 3:24-cv-02534 (N.D. Cal.), in the U.S. District Court for the Northern District of California against the Company and three of its officers. The suit purports to be filed on behalf of a class of stockholders who purchased or otherwise acquired Company common stock between September 13, 2022, and October 9, 2023. The suit asserts claims under the Exchange Act for alleged misstatements and omissions regarding the Company's Phase 2b SYMMETRY study. The complaint seeks damages in an unspecified amount. The court appointed lead plaintiffs and lead counsel on August 2, 2024. Lead Plaintiffs filed an amended complaint on September 24, 2024. On November 18, 2024, Defendants filed a motion to dismiss, Lead Plaintiffs filed an Opposition on January 13, 2025, and Defendants filed a Reply on February 21, 2025. A hearing on Defendants' motion to dismiss was held on April 15, 2025. On May 5, 2025, the Court issued an order dismissing the suit in its entirety, without prejudice. On May 26, 2025, Lead Plaintiffs filed a second amended complaint. On June 16, 2025, Defendants moved to dismiss the second amended complaint and on August 15, 2025, the Court again dismissed the suit in its entirety, this time with prejudice. On September 12, 2025, Lead Plaintiffs filed a Notice of Appeal. Lead Plaintiffs' opening brief is due on December 5, 2025. Due to the early stage of this matter, it is not possible to determine the probability or amount of potential related costs. The Company intends to vigorously defend against the lawsuit.

13. Segment Reporting

Operating segments are defined as components of an enterprise for which separate financial information is available and provided to the chief operating decision maker ("CODM"). The Company has one operating and reporting segment, the development of EFX for the treatment of MASH. The Company's CODM is its Chief Executive Officer. The measure of segment profit and loss is reported on the condensed consolidated statements of operations and comprehensive loss as net loss. The measure of segment assets is reported on the condensed consolidated balance sheets as total assets.

The Company has not generated any product revenue to date. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances EFX through clinical development and, ultimately, seek regulatory approval.

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

The following table provides information related to the EFX operating segment based upon the Company's net loss for the three and nine months ended September 30, 2025 and 2024:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Direct third-party EFX expenses [1]	$ 70,213	$ 65,186	$ 192,068	$ 156,648
Indirect third-party EFX expenses [2]	3,599	3,012	11,880	10,615
Personnel and related expenses	7,163	6,037	20,943	17,613
Stock-based compensation	9,261	7,468	27,100	22,522
Non-operating income and expense:				
Interest expense	1,092	1,246	3,418	3,468
Loss on Extinguishment of Loan Payable	1,557	—	1,557	—
Interest and other income, net	(11,319)	(10,244)	(34,170)	(28,830)
Net loss	$ 81,566	$ 72,705	$ 222,796	$ 182,036
Reconciliation of Net loss				
Adjustments and reconciling items	—	—	—	—
Net loss	$ 81,566	$ 72,705	$ 222,796	$ 182,036

(1) Includes clinical research, contract manufacturing, technical consulting, product licensing and other expenses that are directly related to the development of EFX.

(2) Includes professional services, insurance and other expenses, both R&D and general and administrative, that indirectly support the development of EFX.

14. Subsequent event

In October 2025, the 1,958,247 pre-funded warrants outstanding as of September 30, 2025 (see Note 7) were exercised in exchange for 1,958,241 shares of common stock.

Agreement and Plan of Merger

On October 9, 2025, the Company entered into the Merger Agreement with Novo and Merger Sub, providing for the Merger of Merger Sub with and into the Company, with the Company surviving the Merger as a wholly owned subsidiary of Novo.

At the effective time of the Merger (the "Effective Time"), each share of common stock, par value $0.0001 per share, of the Company ("Company common stock") issued and outstanding immediately prior to the Effective Time (other than Excluded Shares and Dissenting Shares (as defined in the Merger Agreement)) will automatically be cancelled and converted into the right to receive (i) cash in an amount equal to $54.00, without interest thereon and subject to any applicable tax withholdings and (ii) one contingent value right (a "CVR") representing the right to receive $6.00 in cash, without interest and subject to any applicable tax withholdings, if a specified milestone is achieved, pursuant to the CVR Agreement (as defined in the Merger Agreement).

Consummation of the Merger is subject to customary closing conditions, including, without limitation, the absence of certain legal restraints preventing or otherwise making illegal the consummation of the Merger, no Material Adverse Effect (as defined in the Merger Agreement) with respect to the Company having occurred since the date of the Merger Agreement that is continuing, the expiration or termination of any waiting periods under the Hart-Scott-Rodino

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

Antitrust Improvements Act of 1976, as amended (the "HSR Act") applicable to the Merger, the obtainment of any clearance or approval applicable to the Merger under the antitrust and foreign direct investment laws of other applicable foreign jurisdictions, and the adoption of the Merger Agreement by holders of Company common stock representing at least a majority of the outstanding Company common stock.

The parties expect the Merger and the other transactions contemplated by the Merger Agreement to close around year end. Following completion of the Merger, the Company common stock will no longer be publicly listed.

The Merger Agreement contains certain termination rights for the Company and Novo. If the Merger Agreement is terminated under certain specified circumstances, the Company will be required to pay Novo a fee of $165,000. If the Merger Agreement is terminated under other specified circumstances, Novo will be required to pay the Company a fee of $185,000.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion should be read in conjunction with our financial statements and accompanying footnotes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and related notes contained in our Annual Report on Form 10-K for the year ended December 31, 2024. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Because of many factors, including those factors set forth in the "Part II, Item 1A., Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Overview

We are a clinical-stage company dedicated to developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, including metabolic dysfunction-associated steatohepatitis, or MASH, formerly known as non-alcoholic steatohepatitis, or NASH. MASH is a severe form of metabolic dysfunction-associated steatotic liver disease, or MASLD, formerly known as nonalcoholic fatty liver disease, or NAFLD, characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, cancer and death. Our lead product candidate, efruxifermin, or EFX, is an analog of fibroblast growth factor 21, or FGF21, which is an endogenously expressed hormone that protects against cellular stress and regulates metabolism of lipids, carbohydrates and proteins throughout the body. We have an ongoing, global Phase 3 program called SYNCHRONY, which is comprised of three clinical trials (*Outcomes, Histology, and Real-World*) with an expected total enrollment of about 3,500 patients, which is designed to support applications for marketing approval for patients with pre-cirrhotic MASH (F2-F3) and compensated cirrhosis (F4) due to MASH. The SYNCHRONY program builds on two biopsy-based Phase 2b trials in corresponding patient populations, with a combined total of over 300 patients treated for up to 96 weeks. Based on the statistically significant reversal of cirrhosis and fibrosis regression among patients with either biopsy-confirmed compensated cirrhosis (F4) due to MASH or pre-cirrhotic MASH (F2-F3) observed in our Phase 2b clinical trials, we believe EFX has the potential, if approved, to be an important medicine for treating MASH.

Results from five randomized, double-blind, placebo-controlled clinical trials evaluating EFX have been reported, and across all trials reported to date a total of 385 adult patients with either MASH and/or type 2 diabetes have been treated with EFX and evaluated for up to 96 weeks. An additional 66 healthy volunteers or patients with severe hepatic impairment were evaluated in open label, single-dose clinical pharmacology studies.

In January 2025, we reported preliminary topline week 96 results from SYMMETRY, a Phase 2b trial that evaluated the efficacy and safety of EFX in patients with biopsy-confirmed compensated cirrhosis (F4), Child-Pugh Class A, due to MASH. At week 96, among patients with baseline and week 96 biopsies (n=134), 39% of patients treated with 50mg EFX (n=46) (p=0.009) experienced reversal of cirrhosis with no worsening of MASH, compared to 15% for placebo (n=47). On May 9, 2025, The New England Journal of Medicine published an article on the SYMMETRY results titled, "Efruxifermin in Compensated Liver Cirrhosis Caused by MASH" (N Engl J Med 2025;392:2413-2424).

In March 2024, we reported preliminary topline week 96 results from HARMONY, a Phase 2b trial that evaluated the efficacy and safety of EFX in patients with pre-cirrhotic MASH, fibrosis stage 2 or 3 (F2-F3). The trial previously met its primary endpoint of ≥1 stage improvement in fibrosis with no worsening of MASH after 24 weeks of treatment for both the 50mg EFX (41%) and 28mg EFX (39%) dose groups, compared to 20% for the placebo arm. At week 96, the response rates on this endpoint increased to 75% (p<0.001) for 50mg EFX and 46% (p=0.07) for 28mg EFX, compared to 24% for placebo.

EFX has been reported to be generally well-tolerated across clinical trials of EFX to date. Most adverse events, or AEs, were mild or moderate. Diarrhea, nausea and vomiting as well as injection site reactions were generally the most common AEs. Treatment-emergent AEs leading to discontinuation through each study's primary analysis period have been low, ranging from less than 5% in patients with F1-F3 MASH to less than 10% in subjects with compensated cirrhosis due to MASH (F4).

Enrollment for a multi-trial, global Phase 3 program called SYNCHRONY began in the fourth quarter of 2023. The Phase 3 SYNCHRONY program consists of three trials, SYNCHRONY *Outcomes*, SYNCHRONY *Histology*, and SYNCHRONY *Real-World*. SYNCHRONY *Outcomes* is a two-cohort trial evaluating EFX for treatment of patients with compensated cirrhosis (F4), Child-Pugh Class A, due to MASH. SYNCHRONY *Histology* is a two-cohort trial evaluating EFX for treatment of patients with pre-cirrhotic MASH, fibrosis stage 2 or 3 (F2-F3). SYNCHRONY *Real-World* is evaluating EFX for treatment of patients with MASLD or MASH (F1-F4, compensated). In January 2025, we announced the completion of enrollment of the double-blind portion of SYNCHRONY *Real-World*. Results from the SYNCHRONY *Real-World* trial are expected in the first half of 2026.

In five separate clinical trials in patients with MASH and/or type 2 diabetes, EFX has been observed to reverse fibrosis, resolve steatohepatitis, and help restore healthy metabolism to the whole body. Consequently, we believe EFX holds the potential to be an important medicine for treatment of MASH, if approved. We also believe EFX may be able to be used in combination with other therapies for potentially greater effect in certain subpopulations, particularly among the substantial proportion of patients with both MASH and type 2 diabetes who are expected to be treated with GLP-1 therapeutics to manage their diabetes and/or obesity.

We were incorporated in January 2017 and have devoted substantially all of our efforts to organizing and staffing our company, business planning, raising capital, in-licensing rights to EFX, research and development activities for EFX, building our intellectual property portfolio, exploring pipeline expansion opportunities, and providing general and administrative support for these operations. Since our initial public offering (“IPO”) in June 2019, we have raised capital primarily through the sale of our common stock in follow-on public offerings, registered direct offerings and ATM offerings. We have incurred significant operating losses since inception. Our ability to generate product revenue as a standalone company in the event that the merger with Novo is not completed that is sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of EFX, if approved, and any future product candidates. Our net losses were $81.6 million and $72.7 million for the three months ended September 30, 2025 and 2024, respectively. Our net losses were $252.1 million and $151.8 million for the years ended December 31, 2024 and 2023, respectively. As of September 30, 2025, we had an accumulated deficit of $1,049.0 million.

If the merger with Novo is not completed, we expect to continue to incur significant expenses for at least the next several years as we advance EFX through later-stage clinical development, develop additional product candidates and seek regulatory approval of any product candidates that complete clinical development. In addition, if we obtain marketing approval for any product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

If the merger with Novo is not completed, we may also incur expenses in connection with the in-licensing or acquisition of additional product candidates. As a result, we would need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we could generate significant revenue from product sales, if ever, we would expect to finance our operations through the sale of equity, debt financings, or other capital sources, which may include collaborations with other companies or other strategic transactions. In that event, we may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If the merger with Novo is not completed and we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability if the merger with Novo is not completed. In that event, even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2025, we had cash, cash equivalents, short-term and long-term marketable securities of $988.3 million.

Agreement and Plan of Merger

On October 9, 2025, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Novo and NN Invest Sub, Inc., a Delaware corporation and a direct or indirect wholly-owned subsidiary of Novo ("Merger

Sub"), providing for the merger of Merger Sub with and into the Company (the "Merger"), with the Company surviving the Merger as a wholly owned subsidiary of Novo.

At the effective time of the Merger (the "Effective Time"), each share of Company common stock issued and outstanding immediately prior to the Effective Time (other than Excluded Shares and Dissenting Shares (as defined in the Merger Agreement)) will automatically be cancelled and converted into the right to receive (i) cash in an amount equal to $54.00, without interest thereon and subject to any applicable tax withholdings and (ii) one contingent value right (a "CVR") representing the right to receive $6.00 in cash, without interest and subject to any applicable tax withholdings, if a specified milestone is achieved, pursuant to the CVR Agreement (as defined in the Merger Agreement).

Consummation of the Merger is subject to customary closing conditions, including, without limitation, the absence of certain legal restraints preventing or otherwise making illegal the consummation of the Merger, no Material Adverse Effect (as defined in the Merger Agreement) with respect to the Company having occurred since the date of the Merger Agreement that is continuing, the expiration or termination of any waiting periods under Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act") applicable to the Merger, the obtainment of any clearance or approval applicable to the Merger under the antitrust and foreign direct investment laws of other applicable foreign jurisdictions, and the adoption of the Merger Agreement by holders of Company common stock representing at least a majority of the outstanding Company common stock.

The parties expect the Merger and the other transactions contemplated by the Merger Agreement to close around year end. Following completion of the Merger, the Company common stock will no longer be publicly listed.

The Merger Agreement contains certain termination rights for the Company and Novo. If the Merger Agreement is terminated under certain specified circumstances, the Company will be required to pay Novo a fee of $165.0 million. If the Merger Agreement is terminated under other specified circumstances, Novo will be required to pay the Company a fee of $185.0 million.

Components of our results of operations

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts for EFX or additional product candidates that we may develop in the future are successful and result in marketing approval or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred in connection with the development of EFX, as well as unrelated discovery stage program expenses. We expense research and development costs as incurred. These expenses include:

- employee-related expenses, including salaries, related benefits and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred under agreements with CROs that are primarily engaged in the oversight and conduct of our clinical trials; CMOs that are primarily engaged to provide drug substance and product for our clinical trials, research and development programs, as well as investigative sites and consultants that conduct our clinical trials, nonclinical studies and other scientific development services;
- the cost of acquiring and manufacturing nonclinical and clinical trial materials, including manufacturing registration and validation batches;
- costs related to compliance with quality and regulatory requirements; and
- payments made under third-party licensing agreements.

Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Product candidates in later stages of clinical development, such as EFX, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned clinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of EFX and any future product candidates.

Our clinical development costs may vary significantly based on factors such as:

- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients enrolled in clinical trials;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- any setbacks or delays to the initiation or completion of preclinical or non-clinical studies, product development or clinical trials;
- the cost and timing of manufacturing our product candidates, including on account of any disruption or delays to the supply of our product candidates;
- the phase of development of our product candidates; and
- the efficacy and safety profile of our product candidates.

The successful development and commercialization of product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of nonclinical and clinical development activities;
- the number and scope of nonclinical and clinical programs we decide to pursue;
- the ability to raise necessary additional funds;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current development program and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of drug substance, drug product, and delivery devices utilized in the production of our product candidate;
- establishing and maintaining agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidate, if and when approved;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of our product candidate, if approved, by patients, the medical community and third-party payors;
- competition with other products;
- the impacts of a pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, on the supply of our product candidate and ability to successfully initiate and complete preclinical and non-clinical studies

and clinical trials, to receive regulatory approval for our product candidate and to commercialize our product candidate, if approved; and
- a continued acceptable safety profile of our therapy following approval.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and administrative expenses

General and administrative expenses consist primarily of salaries, related benefits and stock-based compensation expense for personnel in executive, finance, corporate and business development, and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative travel expenses; marketing expenses and other operating costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support development of EFX and our continued research activities. We also anticipate that we will incur increased accounting, audit, legal, tax, regulatory, compliance, and director and officer insurance costs, as well as investor and public relations expenses associated with maintaining compliance with exchange listing and SEC requirements.

Interest expense

Interest expense consists primarily of interest expense on our term loan with Hercules, which was repaid in full on September 23, 2025.

Other income

Other income consists primarily of interest income earned on our cash, cash equivalents and short- and long-term marketable securities.

Results of operations

Comparison of the three months ended September 30, 2025 and 2024

The following table summarizes our results of operations for the three months ended September 30, 2025 and 2024:

	Three Months Ended September 30,			
	2025	2024	$ Change	% Change
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 78,883	$ 72,232	$ 6,651	9 %
General and administrative	11,353	9,471	1,882	20 %
Total operating expenses	90,236	81,703	8,533	10 %
Loss from operations	(90,236)	(81,703)	(8,533)	10 %
Interest expense	(1,092)	(1,246)	154	(12) %
Loss on Extinguishment of Loan Payable	(1,557)	—	(1,557)	n/a
Interest and other income, net	11,319	10,244	1,075	10 %
Net loss	$ (81,566)	$ (72,705)	$ (8,861)	12 %

Research and development expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2025 and 2024:

	Three Months Ended September 30,			
	2025	2024	$ Change	% Change
	(in thousands, except percentages)			
Research and development expenses:				
Direct EFX program expenses	$ 70,213	$ 65,186	$ 5,027	8 %
Personnel and other R&D related expenses	8,670	7,046	1,624	23 %
Total research and development expenses	$ 78,883	$ 72,232	$ 6,651	9 %

Research and development expenses were $78.9 million and $72.2 million for the three months ended September 30, 2025 and 2024, respectively, an increase of $6.7 million. Direct costs for our EFX program increased $5.0 million, attributed primarily to a $5.5 million net increase in CRO expenses for our ongoing clinical trials. Expenses for our Phase 3 SYNCHRONY program increased $8.2 million as that program advanced, while expenses for our Phase 2b SYMMETRY and HARMONY clinical trials decreased $2.7 million as those trials were winding down. Personnel and other research and development related expenses increased $1.6 million, including a $0.9 million increase in wage and wage-related expenses resulting from increased staff and a $0.8 million increase in stock-based compensation. We expect that our research and development expenses will increase substantially in the near term and in the future, due to planned manufacturing and clinical development activities necessary to support the ongoing development of EFX.

General and administrative expenses

General and administrative expenses were $11.4 million and $9.5 million for the three months ended September 30, 2025 and 2024, respectively, an increase of $1.9 million, attributable to a $0.2 million increase in wage and wage-related expenses, a $1.0 million increase in stock-based compensation and $0.7 million increase in legal and other third-party professional services.

Interest expense

Interest expense for the three months ended September 30, 2025 and 2024 was $1.1 million and $1.2 million, respectively, related to the Hercules term loan.

Loss on Extinguishment of Loan Payable

Loss on Extinguishment of Loan Payable for the three months ended September 30, 2025 was $1.6 million, related to the repayment in full of the Hercules term loan on September 23, 2025.

Interest and other income

Interest and other income, net were $11.3 million and $10.2 million for the three months ended September 30, 2025 and 2024, respectively, an increase of $1.1 million, resulting primarily from investment earnings on the $402.5 million that we raised from a follow-on public offering in January 2025.

Comparison of the nine months ended September 30, 2025 and 2024

The following table summarizes our results of operations for the nine months ended September 30, 2025 and 2024:

	Nine Months Ended September 30,			
	2025	2024	$ Change	% Change
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 217,704	$ 178,204	$ 39,500	22 %
General and administrative	34,287	29,194	5,093	17 %
Total operating expenses	251,991	207,398	44,593	22 %
Loss from operations	(251,991)	(207,398)	(44,593)	22 %
Interest expense	(3,418)	(3,468)	50	(1) %
Loss on Extinguishment of Loan Payable	(1,557)	—	(1,557)	n/a
Interest and other income, net	34,170	28,830	5,340	19 %
Net loss	$ (222,796)	$ (182,036)	$ (40,760)	22 %

Research and development expenses

The following table summarizes our research and development expenses incurred during the nine months ended September 30, 2025 and 2024:

	Nine Months Ended September 30,			
	2025	2024	$ Change	% Change
	(in thousands, except percentages)			
Research and development expenses:				
Direct EFX program expenses	$ 192,068	156,648	$ 35,420	23 %
Personnel and other R&D related expenses	25,636	21,556	4,080	19 %
Total research and development expenses	$ 217,704	$ 178,204	$ 39,500	22 %

Research and development expenses were $217.7 million and $178.2 million for the nine months ended September 30, 2025 and 2024, respectively, an increase of $39.5 million. Direct costs for our EFX program increased $35.4 million, attributed primarily to a $11.4 million increase in CMO expenses to meet anticipated EFX product demand and a $23.6 million net increase in CRO expenses for our ongoing clinical trials. Expenses for our Phase 3 SYNCHRONY program increased $28.8 million as that program advanced, while expenses for our Phase 2b SYMMETRY and HARMONY clinical trials decreased $5.2 million as those trials were winding down. Personnel and other research and development related expenses increased $4.1 million, including a $2.6 million increase in wage and wage-related expenses resulting from increased staff and a $2.4 million increase in stock-based compensation and a $0.9 million decrease in other R&D related expenses. We expect that our research and development expenses will increase substantially in the near term and in the future, due to planned manufacturing and clinical development activities necessary to support the ongoing development of EFX.

General and administrative expenses

General and administrative expenses were $34.3 million and $29.2 million for the nine months ended September 30, 2025 and 2024, respectively, an increase of $5.1 million, attributable to a $0.7 million increase in wage and wage-related expenses, a $2.2 million increase in stock-based compensation and a $2.2 million increase in legal and other third-party professional services.

Interest expense

Interest expense for the nine months ended September 30, 2025 and 2024 was $3.4 million and $3.5 million, respectively, related to the Hercules term loan.

Loss on Extinguishment of Loan Payable

Loss on Extinguishment of Loan Payable for the nine months ended September 30, 2025 was $1.6 million, related to the repayment in full of the Hercules term loan on September 23, 2025.

Interest and other income

Interest and other income, net were $34.2 million and $28.9 million for the nine months ended September 30, 2025 and 2024, respectively, an increase of $5.3 million, resulting primarily from investment earnings on the $402.5 million that we raised from a follow-on public offering in January 2025.

Liquidity and capital resources

On October 9, 2025, the Company announced that the Company entered into the Merger Agreement with Novo and Merger Sub. In the Merger Agreement, we have agreed to various covenants, including, among others, agreements to conduct our business in the ordinary course consistent with past practice in all material respects during the period between the execution of the Merger Agreement and the Effective Time. Outside of certain limited exceptions, we may not take, authorize, or agree or commit to take, certain actions without Novo's consent, including, but not limited to: (i) acquiring businesses and disposing significant assets; (ii) incurring capital expenditures above specified thresholds; (iii) issuing equity; (iv) incurring indebtedness; and (v) repurchasing or paying dividends on ordinary shares. We do not believe these restrictions will prevent us from being able to fund our operations, working capital needs or capital expenditure requirements.

We have incurred significant operating losses from our inception through September 30, 2025. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, if at all, if the merger with Novo is not completed and we remain independent. Since our IPO in June 2019, we have raised capital primarily through the sale of our common stock in follow-on public offerings, registered direct offerings and At-the-Market, or ATM, offerings. In January 2025, we raised gross proceeds of $402.5 million from a follow-on public offering of our common stock and pre-funded warrants and $10.6 million through the sale of common stock under an ATM offering.

From our inception through September 30, 2025, these and other funding sources have provided gross proceeds totaling $1,910.4 million. As of September 30, 2025, we had cash, cash equivalents short and long-term marketable securities of $988.3 million. We have invested our cash resources primarily in liquid money market accounts, U.S Treasuries and agency securities, commercial paper and corporate debt securities.

The following table summarizes our cash flows for the periods indicated:

	Nine Months Ended September 30,	
	2025	2024
	(in thousands)	
Net cash (used in) operating activities	$ (183,081)	$ (163,017)
Net cash (used in) investing activities	(346,062)	(124,980)
Net cash provided by financing activities	364,937	369,855
Net (decrease) increase in cash and cash equivalents	$ (164,206)	$ 81,858

Cash flows from operating activities

Cash used in operating activities for the nine months ended September 30, 2025 was $183.1 million, consisting of a net loss of $222.8 million offset by non-cash charges of $21.5 million, including $27.1 million of stock-based compensation expense, a $1.6 million loss on extinguishment of debt related to the term loan with Hercules and $7.8 million in amortization of premiums and discounts on our marketable equity securities, and changes in our operating assets and liabilities of $18.3 million. The changes in operating assets and liabilities were primarily due to the timing of prepayments and payments to our CMOs and CROs for ongoing clinical trial and manufacturing activities.

Cash used in operating activities for the nine months ended September 30, 2024 was $163.0 million, consisting of a net loss of $182.0 million offset by non-cash charges of $14.6 million, including $22.5 million of stock-based compensation expense, and changes in our operating assets and liabilities of $4.4 million. The changes in operating assets and liabilities were primarily due to the timing of prepayments and payments to our CMOs and CROs for ongoing clinical trial and manufacturing activities.

Cash flows from investing activities

Cash used in investing activities for the nine months ended September 30, 2025 was $346.1 million, resulting from $732.5 million in purchases of short-term and long-term marketable securities offset by $386.4 million of short-term marketable securities which matured.

Cash used in investing activities for the nine months ended September 30, 2024 was $125.0 million, resulting mainly from $436.3 million in purchases of short-term and long-term marketable securities offset by $312.3 million of short- and long-term marketable securities which matured.

Cash flows from financing activities

Cash provided by financing activities for the nine months ended September 30, 2025 was $364.9 million, including primarily $378.4 million from a follow-on public offering of our common stock and pre-funded warrants in January 2025, $10.4 million from sales of our common stock under our ATM sales agreement, and $13.7 million in proceeds from the exercise of stock options, offset by $37.4 million for the repayment of the term loan to Hercules.

Cash provided by financing activities for the nine months ended September 30, 2024 was $369.9 million, including primarily $344.8 million from a follow-on public offering of our common stock, $10.6 million from sales of our common stock under our ATM sales agreement, $10.0 million from a term loan provided by Hercules, $4.9 million in proceeds from the exercise of stock options and $0.3 million in proceeds from issuance of common stock pursuant to employee stock purchase plan purchases.

Funding requirements

Our future funding requirements will depend on the outcome of the proposed merger with Novo.

Our primary uses of capital are, and we expect will continue to be, research and development services, compensation and related expenses and general overhead costs. We expect to continue to incur significant expenses and operating losses for the foreseeable future. In addition, since the closing of our IPO, we have incurred and expect to continue to incur additional costs associated with operating as a public company. We anticipate that our expenses will increase significantly in connection with our ongoing activities. The timing and amount of our operating expenditures will depend largely on:

- if and when the proposed Merger with Novo is consummated;
- the initiation, progress, timing, costs and results of nonclinical studies and clinical trials for EFX or any future product candidates we may develop;
- timing delays, if any, with respect to preclinical and clinical development of EFX or any future product candidates we may develop as a result of a pandemic, epidemic or outbreak of an infectious disease, or from the impact of geopolitical tensions;
- our ability to maintain our license to EFX from Amgen;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or change their requirements on studies or trials that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any approved product candidate, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;

- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial scale manufacturing;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

If the Merger is not consummated, we expect that we will require additional funding to complete the clinical development of EFX, commercialize EFX, if we receive regulatory approval, and pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for EFX or other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on whether we choose to commercialize EFX ourselves.

If the Merger is not consummated, until we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If the Merger is not consummated and we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and other commitments

On October 9, 2025, the Company entered into the Merger Agreement with Novo and Merger Sub. If we are unable to satisfy certain closing conditions under the Merger Agreement, or if other mutual closing conditions are not satisfied, Novo will not be obligated to complete the Merger. Under certain circumstances detailed in the Merger Agreement, we could be required to pay Novo a termination fee of $165.0 million.

During the nine months ended September 30, 2025, there were no material changes outside the ordinary course of business to our contractual obligations and commitments from those disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations, set forth in Part II, Item 7, in our Annual Report on Form 10-K for the year ended December 31, 2024.

Non-cancelable purchase and other arrangements increased to $90.7 million as of September 30, 2025, compared to $25.6 million as of December 31, 2024, which is primarily attributable to an increase in purchase obligations that support our clinical trial and product manufacturing activities.

Critical accounting policies and estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with United States generally accepted accounting principles. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K for the year ended December 31, 2024 which was filed with the Securities and Exchange Commission on February 28, 2025. There were no material changes to our critical accounting policies through September 30, 2025 from those discussed in our Annual Report on Form 10-K for the year ended December 31, 2024.

Recent accounting pronouncements

See Note 2 to our unaudited condensed consolidated financial statements included in Part I, Item 1, "Notes to Unaudited Condensed Consolidated Financial Statements," of this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our business.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents, short-term and long-term marketable securities of $988.3 million as of September 30, 2025, which consisted primarily of U.S. Treasury-backed securities, corporate debt securities, and money market funds.

The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality and short and long-term duration, according to our board-approved investment policy. Our investments are subject to interest rate risk and could fall in value if market interest rates increase.

A hypothetical 10% relative change in interest rates during any of the periods presented would not have a material impact on our condensed consolidated financial statements.

Foreign Currency Risk

The majority of our transactions occur in U.S. dollars. However, we do have certain transactions that are denominated in currencies other than the U.S. dollar, primarily the Euro and British Pound, and we therefore are subject to foreign exchange risk. The fluctuation in the value of the U.S. dollar against other currencies affects the reported amounts of expenses, assets and liabilities primarily associated with a limited number of manufacturing activities. The effect of a hypothetical 10% change in foreign currency exchange rates applicable to our business would not have had a material impact on our condensed consolidated financial statements for the nine months ended September 30, 2025 and 2024.

Inflation Risk

Although we do not believe that inflation has had a material effect on our business, financial position or results of operations to date, we may experience some effect in the near future (especially if inflation rates continue to rise) due to an impact on the costs to conduct clinical trials, manufacturing and supply costs, labor costs we incur to attract and retain qualified personnel, and other operational costs. Inflationary costs could adversely affect our business, financial condition and results of operations.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2025. Disclosure control and procedures include, without limitation, controls and procedures designed to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of September 30, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the nine months ended September 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in lawsuits, claims, investigations and proceedings, consisting of intellectual property, commercial, employment and other matters which arise in the ordinary course of business. On April 26, 2024, a purported stockholder of the Company filed a lawsuit, captioned Klobus v. Akero Therapeutics, Inc., No. 3:24-cv-02534 (N.D. Cal.), in the U.S. District Court for the Northern District of California against the Company and three of its officers. The suit purports to be filed on behalf of a class of stockholders who purchased or otherwise acquired Company common stock between September 13, 2022, and October 9, 2023. The suit asserts claims under the Exchange Act for alleged misstatements and omissions regarding the Company's Phase 2b SYMMETRY study. The complaint seeks damages in an unspecified amount. The court appointed lead plaintiffs and lead counsel on August 2, 2024. Lead Plaintiffs filed an amended complaint on September 24, 2024. On November 18, 2024, Defendants filed a motion to dismiss the amended complaint. On May 5, 2025, the Court issued an order dismissing the suit in its entirety, without prejudice. On May 26, 2025, Lead Plaintiffs filed a second amended complaint. On June 16, 2025, Defendants moved to dismiss the second amended complaint and on August 15, 2025, the Court again dismissed the suit in its entirety, this time with prejudice. On September 12, 2025, Lead Plaintiffs filed a Notice of Appeal. Lead Plaintiffs' opening brief is due on December 5, 2025. Due to the early stage of this matter, it is not possible to determine the probability or amount of potential related costs. The Company intends to vigorously defend against the lawsuit.

Item 1A. Risk Factors.

In evaluating the Company and our business, careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q and in other documents that we file with the SEC. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occur, our business, prospects, financial condition, results of operations and cash flow could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks facing the Company. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition, results of operations or cash flow.

Risks Related to the Pending Transaction with Novo

We may not complete the pending transaction with Novo within the time frame we anticipate or at all, which could have an adverse effect on our business, financial results, and/or operations.

On October 9, 2025, we announced that we entered into the Merger Agreement with Novo and Merger Sub, providing for the Merger of Merger Sub with and into the Company, with the Company surviving the Merger as a wholly owned subsidiary of Novo.

Consummation of the Merger is subject to customary closing conditions, including, without limitation, the absence of certain legal restraints preventing or otherwise making illegal the consummation of the Merger, no Material Adverse Effect with respect to the Company having occurred since the date of the Merger Agreement that is continuing, the expiration or termination of any waiting periods under the HSR Act applicable to the Merger, the obtainment of any clearance or approval applicable to the Merger under the antitrust and foreign direct investment laws of other applicable foreign jurisdictions, and the adoption of the Merger Agreement by holders of Company common stock representing at least a majority of the outstanding Company common stock. In addition, the Merger Agreement may be terminated under certain specified circumstances, including, but not limited to, a change in the recommendation of our board of directors or a termination of the Merger Agreement by us to enter into an agreement for a "Superior Offer," as defined in the Merger Agreement. As a result, we cannot assure you that the transaction with Novo will be completed, or that, if completed, it will be exactly on the terms set forth in the Merger Agreement or within the expected time frame.

If the transaction is not completed within the expected time frame or at all, we may be subject to a number of material risks. The price of Company common stock may decline to the extent that current market prices of Company common stock reflect a market assumption that the transaction will be completed. We could be required to pay Novo a termination fee of $165.0 million if the Merger Agreement is terminated under specific circumstances described in the Merger Agreement. The failure to complete the transaction also may result in negative publicity and negatively affect our relationship with our stockholders, employees, collaborators, customers, regulators, and other business partners. We

may also be required to devote significant time and resources to litigation related to any failure to complete the Merger or related to any enforcement proceeding commenced against us to perform our obligations under the Merger Agreement.

The pendency of the transaction with Novo could adversely affect our business, financial results and/or operations.

Our efforts to complete the transaction could cause substantial disruptions in, and create uncertainty surrounding, our business, which may materially adversely affect our results of operation and our business. Uncertainty as to whether the transaction will be completed may affect our ability to recruit prospective employees or to retain and motivate existing employees. Employee retention may be particularly challenging while the transaction is pending because employees may experience uncertainty about their roles following consummation of the transaction. A substantial amount of our management's and employees' attention is being directed toward the completion of the transaction and thus is being diverted from our day-to-day operations. Uncertainty as to our future could adversely affect our business and our relationship with collaborators, vendors, customers, regulators, and other business partners. For example, vendors, collaborators, and other counterparties may defer decisions concerning working with us or seek to change existing business relationships with us. Changes to or termination of existing business relationships could adversely affect our results of operations and financial condition, as well as the market price of Company common stock. The adverse effects of the pendency of the transaction could be exacerbated by any delays in completion of the transaction or termination of the Merger Agreement.

While the Merger Agreement is in effect, we are subject to restrictions on our business activities.

While the Merger Agreement is in effect, we are subject to restrictions on our business activities, generally requiring us to conduct our business in the ordinary course consistent with past practice in all material respects, and subjecting us to a variety of specified restrictions absent Novo's prior consent. These limitations include, among other things, restrictions on our ability to acquire other businesses and assets, dispose of our assets, make investments, enter into certain contracts, repurchase or issue securities, pay dividends, make capital expenditures, take certain actions relating to intellectual property, amend our organizational documents, and incur indebtedness. These restrictions could prevent us from pursuing strategic business opportunities, taking actions with respect to our business that we may consider advantageous and responding effectively and/or timely to competitive pressures and industry developments, and may, as a result, materially and adversely affect our business, results of operations and financial condition.

In certain instances, the Merger Agreement requires us to pay a termination fee to Novo, which could require us to use available cash that would have otherwise been available for general corporate purposes.

Under the terms of the Merger Agreement, we may be required to pay Novo a termination fee of $165.0 million if the Merger Agreement is terminated under specific circumstances described in the Merger Agreement, including, but not limited to, in connection with a change in the recommendation of our Board of Directors or a termination of the Merger Agreement by us to enter into an agreement for a "Superior Offer," as defined in the Merger Agreement. If the Merger Agreement is terminated under such circumstances, the termination fee we may be required to pay under the Merger Agreement may require us to use available cash that would have otherwise been available for general corporate purposes and other uses. For these and other reasons, termination of the Merger Agreement could materially and adversely affect our business operations and financial condition, which in turn would materially and adversely affect the price of Company common stock.

We have incurred, and will continue to incur, direct and indirect costs as a result of the pending transaction with Novo.

We have incurred, and will continue to incur, significant costs and expenses, including fees for professional services and other transaction costs, in connection with the pending transaction. We must pay substantially all of these costs and expenses whether or not the transaction is completed.

There are a number of factors beyond our control that could affect the total amount or the timing of these costs and expenses.

Risks Related to the Clinical Development and Manufacturing of our Product Candidate

Risks Related to Clinical Development

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with MASH, significant competition for recruiting such patients in clinical trials, and restrictions on patients and investigators related to outbreaks of infectious diseases or public health crises.

Identifying and qualifying patients to participate in clinical trials is critical to our success. We may encounter delays in enrolling or be unable to enroll or retain a sufficient number of patients in our ongoing Phase 3 SYNCHRONY studies or any other future clinical trials. In particular, as a result of the inherent difficulties in diagnosing MASH and the significant competition for recruiting patients with MASH in clinical trials, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all. In addition, enrollment in Phase 3 clinical trials may be adversely affected by the March 2024 marketing approval of Rezdiffra™ or the potential marketing approvals for one or more investigational MASH drugs.

Factors that may generally affect patient enrollment include:

- the size and nature of the patient population;
- the number and location of clinical sites we enroll;
- the impact of geopolitical tensions, such as the conflict in the Middle East, including between India and Pakistan, on clinical trial sites, such as those in India, Turkey and Israel, where clinical sites have been activated to participate in our Phase 3 SYNCHRONY program;
- the ability of our clinical sites to maintain adequate personnel;
- competition with other companies for clinical sites or patients;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain patient consents;
- risk that enrolled participants will drop out before completion;
- the availability of marketed therapies; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

In addition, if any significant adverse events or other side effects are observed in any of our clinical trials, it may make it more difficult for us to recruit patients to our clinical trials and patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays, which would increase our costs and have an adverse effect on our company.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. We understand that a number of pharmaceutical companies, including AstraZeneca PLC/MedImmune LLC, Boehringer Ingelheim AG, Eisai, Inc., Eli Lilly and Company, GSK plc, Johnson & Johnson, Merck & Co., Inc., Novo Nordisk A/S, Pfizer Inc. and Roche Holding AG, as well as large and small biotechnology companies such as Aligos Therapeutics, Inc., Alnylam Pharmaceuticals, Inc., Altimmune, Inc., Amgen, Inc., Apollo Therapeutics, Arrowhead Pharmaceuticals, Inc., Cirius Therapeutics, Inc., Corcept Therapeutics, Inc., D&D Pharmatech, Inc., Eccogene Co., Ltd., 89bio, Galectin Therapeutics Inc., Galmed Pharmaceuticals, Ltd., Hanmi Pharmaceutical Company, Ltd., HighTide Therapeutics, Inc., Inventiva Pharma SA, Ionis Pharmaceuticals, Inc., Madrigal Pharmaceuticals, Inc., MediciNova, Inc., MetaVia, Inc., North Sea Pharmaceuticals, OrsoBio, Inc., Poxel SA, Regeneron Pharmaceuticals, Inc., Sagimet Biosciences, Inc., Sciwind Biosciences Co., Ltd., Tasly Biopharmaceuticals Co., Ltd., Terns Pharmaceuticals, Inc., Viking Therapeutics, Inc., Yichang HEC Changjiang Pharmaceutical Co., Ltd., Yuhan

Corp. and Zhejiang Doer Biologics Co. Ltd. are or may be pursuing the development or marketing of pharmaceuticals that target MASH or metabolic diseases associated with MASH. It is also probable that the number of companies seeking to develop products and therapies for the treatment of serious metabolic diseases, such as MASH, will increase. Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA approval for superior products. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidate or any future product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidate or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Failures or delays in the commencement or completion of, or ambiguous or negative results from our planned clinical trials of our product candidates could result in increased costs to us and could delay, prevent, or limit our ability to generate revenue and continue our business.

We do not know whether the Phase 3 SYNCHRONY program or any future clinical trials will enroll or be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA or comparable foreign regulatory authorities may not authorize us or our investigators to commence our planned clinical trials or any other clinical trials we may initiate, or may suspend our clinical trials, for example, through imposition of a clinical hold, and may request additional data to permit allowance of our Investigational New Drug Application ("IND");
- delays in filing or receiving allowance of additional INDs that may be required;
- lack of adequate funding to continue our clinical trials and nonclinical studies;
- negative results from our ongoing nonclinical studies;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining ethics committee or Institutional Review Board ("IRB") approval to conduct a clinical study at a prospective site or sites;
- challenges in recruiting and enrolling subjects to participate in clinical trials, the proximity of subjects to study sites, eligibility criteria for the clinical study, the nature of the clinical study protocol, the availability of approved effective treatments for the relevant disease, and competition from other clinical study programs for similar indications;
- challenges and delays in activating planned clinical trial sites globally due to the impact of geopolitical tensions, including the escalating conflict in the Middle East;
- severe or unexpected drug-related side effects experienced by subjects in a clinical trial;
- we may decide, or regulatory authorities may require us, to conduct additional nonclinical or clinical trials or abandon product development programs;
- delays in validating, or inability to validate, any endpoints utilized in a clinical trial;

- the FDA or comparable foreign regulatory authorities may disagree with our clinical study design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials; and
- difficulties retaining subjects who have enrolled in a clinical trial but may be prone to withdrawal due to rigors of the clinical trials, lack of efficacy, side effects, personal issues, or loss of interest.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical study may be suspended or terminated by us, the FDA or comparable foreign regulatory authorities, the IRBs at the sites where the IRBs are overseeing a clinical study, a data and safety monitoring board ("DSMB") overseeing the clinical study at issue or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical study operations or study sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including in response to the imposition of a clinical hold;
- unforeseen safety issues or safety signals, including any that could be identified in our ongoing nonclinical studies or clinical trials, adverse side effects or lack of effectiveness;
- changes in government regulations or administrative actions;
- problems with clinical supply materials; and
- lack of adequate funding to continue clinical trials.

Any inability to successfully complete nonclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make changes to a product candidate, such as the drug product-device combination being used in the Phase 3 SYNCHRONY program, we may need to conduct additional nonclinical studies or clinical trials to bridge or demonstrate the comparability of our modified product candidate to earlier versions, which could delay our clinical development plan or marketing approval for our current product candidate and any future product candidates. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Clinical development is uncertain and our clinical trials for EFX and any future product candidates may experience delays, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

We cannot be sure that we will be able to continue development of EFX or submit INDs or similar applications for any future product candidates, on the timelines we expect, if at all. To proceed with our development plans and ultimately commercialization, we may need to conduct and meet regulatory requirements for additional preclinical studies and clinical trials. We cannot be certain of the timely completion or outcomes of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcomes of our preclinical studies and clinical trials will enable any future clinical trials to begin under a proposed protocol.

We rely and will continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We depend and will continue to depend upon third parties, including independent investigators, to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners and others. We expect to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We rely heavily on third parties over the course of our clinical trials, and, as a result, have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with approved clinical trial protocols. Nevertheless, our reliance on third parties does not relieve us of our regulatory responsibilities and we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. We and these third parties are required to comply with good clinical practice ("GCP") requirements, which are regulations and guidelines enforced by the FDA and

comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional nonclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with products produced under current good manufacturing practice ("cGMP") requirements and may require a large number of patients. Our failure or any failure by these third parties to comply with these applicable regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

The third parties who conduct our clinical trials are not our employees and, except for remedies that may be available to us under our agreements with those third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates in a timely manner or at all. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure (including by clinical sites or investigators) to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenues could be delayed significantly.

Risks Related to the Manufacturing of our Product Candidate

The manufacture of our product candidates is complex and we may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing our product candidates, including pre-filled, dual-chamber syringe presentations of our product candidates, are complex, expensive, highly regulated, and subject to multiple risks. Further, as product candidates are developed through nonclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not

achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

In addition, the manufacturing process for any products that we may develop is subject to FDA and other comparable foreign regulatory authority approval processes and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements, including, for example, complying with cGMP, applicable product tracking and tracing requirements and applicable Quality System Regulation ("QSRs"), on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our contract manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging or comparability nonclinical or clinical trials or the repetition of one or more clinical trials, increase clinical study costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations, and growth prospects.

We are subject to many manufacturing risks, any of which could substantially increase our costs, delay clinical programs and limit supply of our product candidates.

We have contracted with a third-party manufacturer, Boehringer Ingelheim, to make EFX drug substance (active pharmaceutical ingredient ("API")) and with another third-party manufacturer, Vetter Pharma International GmbH, or Vetter, to manufacture EFX drug product ("DP") including a DP-device combination for use in Phase 3 studies. We have successfully manufactured API and a DP-device combination under GMP conditions, each of which have been released for use in our ongoing Phase 3 SYNCHRONY program. The formulation used for API manufacture has been modified to enable production of a lyophilized DP rather than the frozen liquid used in Phase 2b studies. This change improves long-term pharmaceutical stability of the DP, making it suitable as the potential commercial presentation. A program of pharmaceutical and clinical studies has shown that the DP-device presentation being used in Phase 3 studies is comparable to that used for Phase 2b studies. We have begun negotiating terms for commercial supply with each of Boehringer Ingelheim and Vetter and expect to enter into final agreements prior to readout of the Phase 3 SYNCHRONY Histology study.

The process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including:

- the manufacturing process is susceptible to product loss due to contamination by adventitious microorganisms, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions. Even minor deviations from normal manufacturing processes could result in reduced production yields and quality as well as other supply disruptions. If microbial, viral, or other contaminants are discovered in our products or in the manufacturing facilities in which our products are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination;
- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, pandemics, epidemics, or outbreaks of infectious disease, financial difficulties of our contract manufacturers, natural disasters, power failures, local political unrest and numerous other factors; and
- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our products. We may also have to record inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more expensive manufacturing alternatives.

The manufacture of EFX requires significant expertise and capital investment, including the development of advanced manufacturing techniques and in-process controls. Manufacturers of these products sometimes encounter difficulties in production, especially during scale-up from the manufacturing process used for early clinical trials to a validated and qualified process needed for pivotal clinical trials and commercial launch. These problems include failure

to meet target production costs and yields, failure to meet product release specifications, including stability of the product, quality assurance system failures, operator error and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any product quality issues relating to the manufacture of our product candidate or any future product candidates will not occur in the future.

We do not have, and we do not currently plan to acquire or build the facilities or internal capabilities to manufacture bulk drug substance, finished drug product or delivery device for use in clinical trials or commercialization. To a large extent, that makes us dependent on the goodwill of our contract manufacturing partners to quickly fix deviations that will inevitably occur during the manufacturing of our product and to manufacture API and/or the DP-device combination in sufficient quantities to meet commercial demand, if approved for marketing. Any delay or interruption in the supply of clinical trial materials on our contract manufacturing partners, could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials altogether. A new lyophilized EFX DP-device combination product for commercial use is being evaluated in the Phase 3 SYNCHRONY program.

We contract with third parties for the manufacture of EFX and the delivery device utilized for EFX and expect to continue to do so for future clinical trials and for commercialization of EFX as well as for any future product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of EFX, or the delivery devices utilized for EFX, or any future product candidates or medicines or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of EFX, delivery devices utilized for EFX or any future product candidates for nonclinical and clinical testing and for commercial supply of any of these product candidates for which we obtain marketing approval. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. To the extent any issues arise with our third-party manufacturers, we may be unable to establish any agreements with any other third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance and safety and pharmacovigilance reporting.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. For our product candidates that are biologic-device combination products, third-party manufacturers may not be able to comply with cGMP regulatory requirements applicable to biologic-device combination products, including applicable provisions of the FDA's drug product cGMP regulations, device cGMP requirements embodied in the FDA's QSR or similar regulatory requirements outside the United States. Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or medicines, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business and results of operations.

If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through an analytical comparability study, that any new

manufacturing process will produce our product candidate according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, in the case of CMOs that supply our product candidate, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply of bulk drug substance or for the manufacture of our drug product-delivery device combination. If any one of our current contract manufacturers cannot perform as agreed to support our ongoing clinical trials or as needed to meet potential commercial demand if EFX is approved, we may be required to replace that manufacturer. Although we believe that there potentially are alternative manufacturers who could manufacture our drug substance or drug product-delivery device combination or any future product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of EFX or any future product candidates or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

Risks Related to Our Business, Industry and Intellectual Property

Risks Related to Business Development

We are heavily dependent on the success of EFX, our only product candidate.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to EFX, which is currently our only product candidate. Accordingly, our business currently depends heavily on the successful development, regulatory approval, and commercialization of EFX. We cannot be certain that EFX will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. If we were required to discontinue development of EFX or if EFX does not receive regulatory approval or fails to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever.

The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing, and distribution of EFX is, and will remain, subject to comprehensive regulation by the FDA and foreign regulatory authorities. Failure to obtain regulatory approval for EFX in the United States, Europe, Japan or other jurisdictions will prevent us from commercializing and marketing EFX in such jurisdictions.

Clinical development of EFX prior to the BALANCED study was conducted by Amgen, Inc. (“Amgen”) in patients with type 2 diabetes. We did not conduct any of the development of EFX related to clinical trials in patients with T2D, and we have relied on Amgen to have conducted such research and development in accordance with the applicable protocol, legal, regulatory, and scientific standards, have accurately reported the results of all nonclinical studies and clinical trials conducted prior to our license of EFX, and have correctly collected and interpreted the data from these studies and trials. To the extent any of the foregoing has not occurred, our expected development time and development costs for EFX may be increased.

Even if we were to successfully obtain approval from the FDA and foreign regulatory authorities for EFX, any approval might contain significant limitations related to use, including limitations on the stage of disease EFX is approved to treat, as well as restrictions for specified age groups, warnings, precautions or contraindications. Furthermore, even if we obtain regulatory approval for EFX, we will still need to develop a commercial infrastructure or

develop relationships with collaborators to commercialize, establish a commercially viable pricing structure and obtain coverage and adequate reimbursement from third-party payors, including government healthcare programs. If we, or any future collaborators, are unable to successfully commercialize EFX, we may not be able to generate sufficient revenue to continue our business.

We have expended and will continue to expend our limited resources to pursue a particular therapeutic candidate or indication, such as our focus on developing EFX for the treatment of MASH, and may fail to capitalize on therapeutic candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have focused our extensive research and development efforts on EFX for the treatment of MASH. Therefore, we have, and in the future may, forego or delay pursuit of opportunities with other therapeutic candidates or for other indications that later prove to have greater commercial potential. We are highly dependent on the success of the future clinical trials of EFX, the outcomes of which are uncertain. Because EFX is our first and only therapeutic candidate, if it encounters safety, efficacy, supply or manufacturing problems, developmental delays, regulatory or commercialization issues or other problems, the value of our platform could be greatly diminished and our development plans could be curtailed and our business would be significantly harmed.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and EFX for the treatment of MASH may not yield any commercially viable therapeutic candidates. If we do not accurately evaluate the commercial potential or target market for a particular therapeutic candidate or misread trends in the biopharmaceutical industry, in particular for serious metabolic diseases, we may relinquish valuable rights to that therapeutic candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such therapeutic candidate.

At any time and for any reason, we may determine that one or more of our discovery programs or pre-clinical or clinical therapeutic candidates or programs does not have sufficient potential to warrant the allocation of resources toward such program or therapeutic candidate. Accordingly, we may choose not to develop a potential therapeutic candidate or elect to suspend, deprioritize or terminate one or more of our discovery programs or preclinical or clinical therapeutic candidates or programs. Suspending, deprioritizing or terminating a program or therapeutic candidate in which we have invested significant resources, means we will have expended resources on a program that will not provide a full return on our investment and may have missed the opportunity to have allocated those resources to potentially more productive uses, including existing or future programs or therapeutic candidates.

If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed and our business will be more vulnerable to any problems that we encounter in developing and commercializing our product candidate.

Our product candidate and any future product candidates must undergo rigorous clinical trials and regulatory approvals, and success in nonclinical studies or earlier-stage clinical trials may not be indicative of results in future clinical trials. EFX and any future product candidates will be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and similar regulatory bodies in other jurisdictions. The approval process is typically lengthy and expensive, and approval is never certain. As a company, our only experience with clinical trials is our completed Phase 2 BALANCED, HARMONY, and SYMMETRY studies, and we have not yet completed the clinical trials required to obtain regulatory approval. We may not be able to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. Our anticipated clinical trials, including our ongoing SYNCHRONY Phase 3 trials, for which we dosed the first patients in the fourth quarter of 2023, may be insufficient to demonstrate that our potential products will be safe or effective. Additional clinical trials may be required if clinical trial results are negative or inconclusive, which will require us to incur additional costs and significant delays.

Success in nonclinical studies and earlier-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the effectiveness and safety of a product candidate. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval for a MASH therapy. In addition, there is a

high failure rate for drugs and products proceeding through clinical trials. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in nonclinical studies and earlier-stage clinical trials. Similarly, the outcome of nonclinical studies may not predict the success of clinical trials. Moreover, data obtained from nonclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of our product development. Additionally, we are developing a pre-filled, dual-chamber syringe presentation of EFX that is considered to be a biologic-device combination product by the FDA, and any biologics license application for EFX will require review and coordination by FDA's drug and device centers prior to approval. Any such delays could negatively impact our business, financial condition, results of operations and prospects. From time to time, we may publish interim 'top-line' or preliminary data from our clinical trials. Preliminary or interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business and financial prospects.

In addition, certain of our hypotheses regarding the potential clinical and therapeutic benefit of EFX compared to other candidates in development for MASH are based on cross-trial comparisons of results that were not derived from head-to-head preclinical studies or clinical trials. These observations, which do not reflect robust comparative analyses, may suggest misleading similarities or differences due to differences in study protocols, conditions and patient populations, and may not be reliable predictors of the relative efficacy or other benefits of EFX compared to other product candidates that are in development for the treatment of MASH.

We may develop EFX, and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.

We may develop EFX and future product candidates in combination with one or more approved therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate EFX or any other future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell EFX or any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval, or if safety, efficacy, manufacturing, or supply issues arise with the drugs we choose to evaluate in combination with EFX or any other product candidate we develop, we may be unable to obtain approval of or market EFX or any other product candidate we develop.

If we are not successful in discovering, developing, receiving regulatory approval for and commercializing EFX and any future product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although we plan to devote a majority of our resources to the continued nonclinical and clinical testing and potential approval of EFX for the treatment of patients with MASH, another key element of our strategy is to discover, develop and commercialize a portfolio of products. We are seeking to do so through the identification and potential development of additional pipeline programs, but our resources are limited, and those that we have are geared towards nonclinical and clinical testing and seeking regulatory approval of EFX for the treatment of patients with MASH. We may also explore strategic collaborations for the development or acquisition of new product candidates, but we may not be successful in entering into such relationships. EFX is our only product candidate in clinical stages of development. Research programs to identify product candidates require substantial technical, financial and human resources, regardless of whether any product candidates are ultimately identified. Our research programs may initially show

promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- an approved product may not be accepted as safe and effective by trial participants, the medical community or third-party payors; and
- intellectual property or other proprietary rights of third parties for product candidates we develop may potentially block our entry into certain markets or make such entry economically impracticable.

Risks Related to our License and Third-Parties

We may be required to make significant payments under our license agreement for EFX.

We acquired worldwide, exclusive rights to EFX pursuant to our license agreement with Amgen, which we refer to as the Amgen Agreement. Under the Amgen Agreement, in consideration for the license, we made an upfront payment of $5.0 million to Amgen and also issued 2,653,333 shares of our Series A convertible preferred stock to Amgen at the time of the initial closing of our Series A Preferred Stock financing in June 2018, with a subsequent 3,205,128 shares of our Series A convertible preferred stock issued at the time of the second closing of the Series A Preferred Stock financing in November 2018. On July 2, 2019, we announced the dosing of the first patient in the BALANCED study of EFX, which resulted in a $2.5 million milestone obligation under the Amgen Agreement. Additionally, we paid Amgen $7.5 million in December 2023 in connection with dosing the first patient in our Phase 3 SYNCHRONY program. As additional consideration for the license, we are required to pay Amgen up to $30.0 million in connection with marketing approvals and aggregate milestone payments of up to $75.0 million upon the achievement of specified commercial milestones. Commencing on the first commercial sale of licensed products, we are obligated to pay tiered royalties of low to high single-digit percentages on annual net sales of the products covered by the license. If milestone or other non-royalty obligations become due, we may not have sufficient funds available to meet our obligations, which will materially adversely affect our business operations and financial condition.

If we breach our license agreement with Amgen related to EFX, we could lose the ability to continue the development and commercialization of EFX.

We are dependent on patents, know-how and proprietary technology in-licensed from Amgen. Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidate or any future product candidates and use our and our licensor's proprietary technologies without infringing the proprietary rights of third parties. Amgen may have the right to terminate the license agreement in full in the event we materially breach or default in the performance of any of the obligations under the license agreement. A termination of the license agreement with Amgen could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Disputes may also arise between us and Amgen, as well as any future potential licensors, regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidate and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

In addition, the Amgen Agreement under which we currently license intellectual property is complex, and certain provisions may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property, or increase what we believe to be our financial or other obligations under the Amgen Agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangement on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

We may seek to establish collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

We may pursue collaborations in order to develop and commercialize EFX and any future product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidate or any future product candidates or bring them to market and generate product revenue.

Risks Related to Employee Matters and Growth

We must attract and retain highly skilled employees in order to succeed. If we are not able to retain our current senior management team and our scientific advisors or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting

and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. We are dependent on the members of our management team and our scientific advisors for our business success. We do not maintain "key person" insurance for any of our key personnel. An important element of our strategy is to take advantage of the research and development expertise of our current management and to utilize the expertise of our scientific advisors in the MASH field. We currently have employment agreements with all of our executive officers. Our employment agreements with our executive officers are terminable by them without notice and some provide for severance and change in control benefits. The loss of any one of our executive officers or key scientific consultants could result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and further commercialization of our product candidate or any future product candidates.

There is intense competition for qualified personnel, including management, in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful research, development and commercialization of EFX or any future product candidates. In particular, we have experienced a very competitive hiring environment in the San Francisco Bay Area, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the law or regulation, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws enforced by the FDA and other similar foreign regulatory bodies, fails to provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, fails to comply with manufacturing standards we have established, fails to comply with healthcare fraud and abuse laws in the United States and similar foreign laws, or fails to report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are also likely to increase. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as

Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

We may encounter difficulties in managing our growth, which could adversely affect our operations.

As of October 31, 2025, we had 74 full-time employees and one part-time employee. As we continue development and pursue the potential commercialization of EFX and other product candidates, as well as function as a public company, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize our product candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

Risks Related to Protecting Our Intellectual Property

Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our success will depend in significant part on our and our current or future licensors', licensees' or collaborators' ability to establish and maintain adequate protection of our intellectual property covering the product candidates we plan to develop, and the ability to develop these product candidates and commercialize the products resulting therefrom, without infringing the intellectual property rights of others. We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking patents intended to cover our products and compositions, their methods of use, and any other inventions that are important to the development of our business. In addition to taking other steps to protect our intellectual property, we have applied for, and intend to continue to apply for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. Our in-licensed patents and patent applications in both United States and certain foreign jurisdictions relate to EFX and related Fc-fusion polypeptides. There can be no assurance that the claims of our patents or any patent application that issues as a patent, will exclude others from making, using or selling our product candidate or any future product candidates or products that are substantially similar to our product candidate or any future product candidates. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. In countries where we have not and do not seek patent protection, third parties may be able to manufacture and sell our product candidate or any future product candidates without our permission, and we may not be able to stop them from doing so.

With respect to patent rights, we do not know whether any of the pending patent applications for our product candidate or any future product candidates will result in the issuance of patents that effectively protect our technologies, processes and product candidates, or if any of our issued patents or our current or future licensors', licensees' or collaborators' issued patents will effectively prevent others from commercializing competitive technologies, processes and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or our current or future licensors, licensees or collaborators were the first to make or file on the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our current or future licensors, licensees or collaborators were the first to file for patent protection of such inventions. There is also no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which could be used by a third party to challenge the validity of our patents, should they issue, or prevent a patent from issuing from a pending patent application. Any of the foregoing could harm our competitive position, business, financial condition, results of operations, and prospects.

Any changes we make to our product candidate or any future product candidates, including formulations that may be required for commercialization, or that cause them to have what we view as more advantageous properties may

not be covered by our existing patents and patent applications, and we may be required to file new applications and/or seek other forms of protection for any such altered product candidates. The patent landscape surrounding the technology underlying our product candidate or any future product candidates is crowded, and there can be no assurance that we would be able to secure patent protection that would adequately cover an alternative to our product candidate or any future product candidates.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current or future licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees or collaborators to perform these activities, which means that these patent applications may not be prosecuted, and these patents enforced, in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, which in recent years have been the subject of much litigation, and, therefore, the issuance, scope, validity, enforceability, and commercial value of any patent claims that we have rights or may obtain cannot be predicted with certainty. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our current or future licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued that protect our technology or product candidates, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our current or future licensors, licensees or collaborators to narrow the scope of the claims of pending and future patent applications, which would limit the scope of patent protection that is obtained, if any. Our and our current or future licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology that is currently claimed in such applications unless and until a patent issues from such applications, and then only to the extent the claims that issue are broad enough to cover the technology being practiced by third parties.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after the resulting products are commercialized. As a result, our owned and in-licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms for our issued patents, where available. This includes in the United States under the Hatch-Waxman Act, which permits a patent term extension of up to five years beyond the original expiration date of the patent as compensation for regulatory delays. However, such a patent term extension cannot lengthen the remaining term of a patent beyond a total of 14 years from the product's approval date. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of product approval. During the period of patent term extension, the claims of a patent are not enforceable for their full scope but are instead limited to the scope of the approved product. In addition, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. In addition, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to the expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, any period during which we have the right to exclusively market our product will be shorter

than we would otherwise expect, and our competitors may obtain approval of and launch products earlier than might otherwise be the case.

Patent terms may be inadequate to protect our competitive position on our product candidate or any future product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. A number of U.S. patents directed to various aspects of EFX will expire in 2029; we currently anticipate that a composition of matter patent will be eligible for patent term extension to 2034. Even if patents covering our product candidate or any future product candidate are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidate or any future product candidate might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may not be able to protect our intellectual property rights throughout the world.

The legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective or effective as that in the United States and we may, therefore, be unable to acquire and enforce intellectual property rights outside the United States to the same extent as in the United States. Whether filed in the United States or abroad, our patent applications may be challenged or may fail to result in issued patents.

In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing or commercializing competing products. Furthermore, others may independently develop or commercialize similar or alternative technologies or drugs, or design around our patents. Our patents may be challenged, invalidated, circumvented or narrowed, or fail to provide us with any competitive advantages. In many foreign countries, patent applications and/or issued patents, or parts thereof, must be translated into the native language. If our patent applications or issued patents are translated incorrectly, they may not adequately cover our technologies; in some countries, it may not be possible to rectify an incorrect translation, which may result in patent protection that does not adequately cover our technologies in those countries.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and certain state laws in the United States. Consequently, we and our licensor may not be able to prevent third parties from practicing our and our licensor's inventions in all countries outside the United States, or from selling or importing products made using our and our licensor's inventions in and into the United States or other jurisdictions. For example, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, the new unitary patent system that came into effect in 2023 would significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes. Competitors may use our and our licensor's technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensor have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidate or any future product candidates and our and our licensor's patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology. This could make it difficult for us and our licensor to stop the infringement of our and our licensor's patents or the marketing of

competing products in violation of our and our licensor's proprietary rights, generally. Proceedings to enforce our and our licensor's patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensor's efforts and attention from other aspects of our business, could put our and our licensor's patents at risk of being invalidated or interpreted narrowly, could place our and our licensor's patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensor. We or our licensor may not prevail in any lawsuits that we or our licensor initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability differ in certain countries, particularly developing countries. For example, China has a heightened requirement for patentability and, specifically, requires a detailed description of medical uses of a claimed drug. In addition, India, certain countries in Europe and certain developing countries, including Thailand, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensor may have limited remedies if patents are infringed or if we or our licensor are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Accordingly, our and our licensor's efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on issued United States patents and most foreign patent applications and patents must be paid to the U.S. Patent and Trademark Office ("USPTO") and foreign patent agencies, respectively, in order to maintain such patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application, examination and issuance processes. While an inadvertent lapse can, in some cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensor fail to maintain the patents and patent applications covering our product candidate or any future product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would have a material adverse effect on our business, financial condition and results of operations.

We may be unable to obtain intellectual property rights or technology necessary to develop and commercialize EFX or any future product candidates.

Several third parties are actively researching and seeking and obtaining patent protection in the MASH field, and there are issued third-party patents and published third-party patent applications in these fields. However, we may not be aware of all third-party intellectual property rights potentially relating to our product candidate or any future product candidates and technologies.

Depending on what patent claims ultimately issue and how courts construe the issued patent claims, as well as depending on the ultimate formulation and method of use of our product candidate or any future product candidates, we may need to obtain a license under such patents. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If a third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable to develop and commercialize one or more of our product candidate or any future product candidates, which would have a material adverse effect on our business, financial condition and results of operations. Moreover, even if we obtain licenses to such intellectual property, but subsequently fail to meet our obligations under our license agreements, or such license agreements are terminated for any other reasons, we may lose our rights to in-licensed technologies.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may

consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, in our activities we also rely substantially on trade secrets, including unpatented know-how, technology and other proprietary materials and information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these steps may be inadequate, we may fail to enter into agreements with all such parties or any of these parties may breach the agreements and disclose our proprietary information and there may be no adequate remedy available for such breach of an agreement. We cannot assure you that our proprietary information will not be disclosed or that we can meaningfully protect our trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing, or unwilling, to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Risks Related to Intellectual Property Litigation

We may become involved in lawsuits or other proceedings to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe our or our licensor's patents or misappropriate or otherwise violate our or our licensor's intellectual property rights. In the future, we or our licensor may initiate legal proceedings to enforce or defend our or our licensor's intellectual property rights, to protect our or our licensor's trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensor to challenge the validity or scope of intellectual property rights we own, control or to which we have rights. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of our or our licensor's patents, requiring us or our licensor to engage in complex, lengthy and costly litigation or other proceedings. These proceedings can be expensive and time-consuming and many of our or our licensor's adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Moreover, the outcome following legal assertions of invalidity and unenforceability is unpredictable. Accordingly, despite our or our licensor's efforts, we or our licensor may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or have rights to, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, if we or our licensor initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensor's patents do not cover the technology in question. An adverse result in any

litigation proceeding could put one or more of our or our licensor's patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

Third-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, revocation, reexamination, *inter partes* review or interference proceedings, or other pre-issuance or post-grant proceedings or other patent office proceedings or litigation in the United States or other jurisdictions provoked by third parties or brought by us or our licensor, may be necessary to determine the inventorship, priority, patentability or validity of inventions with respect to our or our licensor's patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or could require us or our licensor to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our product candidate or any future product candidates without infringing third-party patent rights. Our business could be harmed if the prevailing party does not offer us or our licensor a license on commercially reasonable terms, or at all. Even if we or our licensor obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensor. In addition, if the breadth or strength of protection provided by our or our licensor's patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or any future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into collaborations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, many foreign jurisdictions have rules of discovery that are different than those in the United States and which may make defending or enforcing our or our licensor's patents extremely difficult. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us or our licensor alleging that we or our licensor infringe their intellectual property rights or we or our licensor may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, revocations, reexaminations, *inter partes* review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. These proceedings can be expensive and time-consuming and many of our or our licensor's adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensor can.

An unfavorable outcome in any such proceeding could require us or our licensor to cease using the related technology or developing or commercializing our product candidate or any future product candidates, or to attempt to license rights to it from the prevailing party, which may not be available on commercially reasonable terms, or at all.

We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product

candidate or any future product candidates or force us to cease some of our business operations, which could materially harm our business.

We perform searches of patent and scientific databases in order to identify documents that may be of potential relevance to the freedom-to-operate and/or patentability of our product candidate or any future product candidates. In general, such searches are conducted based on keywords, sequences, inventors/authors and assignees/entities to capture U.S. and European patents and patent applications, PCT publications and scientific journal articles.

The patent landscape around our EFX product candidate is complex, and we may not be aware of all third-party intellectual property rights potentially relating to our product candidate or any future product candidates and technologies. Moreover, it is possible that we are or may become aware of patents or pending patent applications that we think do not relate to our product candidate or any future product candidates or that we believe are invalid or unenforceable, but that may nevertheless be interpreted to encompass our product candidate or any future product candidates and to be valid and enforceable. As to pending third-party applications, we cannot predict with any certainty which claims will issue, if any, or the scope of such issued claims. If any third-party intellectual property claims are asserted against us, even if we believe the claims are without merit, there is no assurance that a court would find in our favor, e.g., on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability and the ability of our licensor to commercialize any product candidates we may develop, and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any such third-party patents (including those that may issue from such applications) were successfully asserted against us or our licensor or other commercialization partners and we were unable to successfully challenge the validity or enforceability of any such asserted patents, then we or our licensor and other commercialization partners may be prevented from commercializing our product candidate or any future product candidates, or may be required to pay significant damages, including treble damages and attorneys' fees if we are found to willfully infringe the asserted patents, or obtain a license to such patents, which may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Any of the foregoing would have a material adverse effect on our business, financial condition and operating results.

We may be subject to claims by third parties asserting that our employees or we have misappropriated a third party's intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain other damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the

assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our current or future collaborators, might not have been the first to make the inventions covered by the issued patents and pending patent applications that we license or may own in the future;
- we, or our current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or our licensing partner initiate legal proceedings against a third party to enforce a patent covering our product candidate or any future product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include *inter partes* review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. A loss of patent protection for our product candidates could have a material adverse impact on our ability to commercialize or license our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

Likewise, patents directed to our proprietary technologies and our product candidates may expire before or soon after our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of

our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, financial condition, prospects and results of operations. A number of U.S. patents directed to various aspects of EFX will expire in 2029; we currently anticipate that a composition of matter patent will be eligible for patent term extension to 2034.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidate or any future product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves technological and legal complexity, and obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances, weakening the rights of patent owners in certain situations or ruling that certain subject matter is not eligible for patent protection. In addition to increasing uncertainty with regard to our and our licensor's ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, the USPTO and equivalent bodies in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensor's ability to obtain new patents or to enforce existing patents and patents we and our licensor may obtain in the future.

Patent reform laws, such as the Leahy-Smith America Invents Act as well as changes in how patent laws are interpreted, could increase the uncertainties and costs surrounding the prosecution of our and our licensor's patent applications and the enforcement or defense of our or our licensor's issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Government Regulation

Risks Related to Obtaining Regulatory Approval

We have limited experience in conducting clinical trials and have never obtained approval for any product candidates, and may be unable to do so successfully.

As a company, other than the completed BALANCED, HARMONY and SYMMETRY studies, we have no experience in designing, conducting or completing clinical trials and have never progressed a product candidate through to regulatory approval. In part because of this lack of experience, our clinical trials may require more time and incur greater costs than we anticipate. We cannot be certain that our clinical trials, including the ongoing SYNCHRONY Phase 3 trials, will begin or conclude on time, if at all. Large-scale trials will require significant additional financial and management resources. Any performance failure on the part of such third parties could delay the clinical development of our product candidate or any future product candidates or delay or prevent us from obtaining regulatory approval or commercializing our current or any future product candidates, depriving us of potential product revenue and resulting in additional losses.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for EFX or any future product candidate would substantially harm our business.

The time required to obtain approval from the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of nonclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions. The FDA and comparable regulatory authorities may change the requirements for approval even after they have reviewed and commented on the design for our clinical

trials. Further, the FDA or comparable regulatory authorities may disagree with our interpretation of data from clinical trials.

EFX or our future product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from nonclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of EFX or any future product candidates to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our nonclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional nonclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program for other reasons. If we were to obtain approval, regulatory authorities may approve EFX or any future product candidates for fewer or more limited indications than we request, may require labeling or a Risk Evaluation and Mitigation Strategy that includes significant use or distribution restrictions or safety warnings, precautions, or contraindications, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

The U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

The U.S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

In 2017, the U.S. Congress and the Trump administration made substantial changes to U.S. policies, which included comprehensive corporate and individual tax reform. In addition, the Trump administration called for significant changes to U.S. trade, healthcare, immigration and government regulatory policy. With the transition to the Biden administration in early 2021, changes to U. S. policy occurred and since the start of the Trump Administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. For example, the One Big Beautiful Bill Act (the "OBBBA") was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. For example, under Section 174 of the Internal Revenue Code of 1986, as amended (the "IRC"), in taxable years beginning after December 31, 2021, expenses that are incurred for research and development performed outside the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and

development performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized. In addition, the OBBBA provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years by filing amended tax returns for such taxable years, and all other taxpayers that are not eligible to make such an election and that amortized expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31, 2024. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Additional time may be required to obtain regulatory approval for our product candidates because they are combination products.

EFX is being developed, and future product candidates may be developed, as combination products that require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug/biologic components. Medical products containing a combination of new drugs, biological products or medical devices may be regulated as "combination products" in the United States and EU. A combination product generally is defined as a product comprised of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. Where approval of the drug or biologic and device is sought under a single application, there could be delays in the approval process due to the increased complexity of the review process and the lack of a well-established review process and criteria. The EMA has a parallel review process in place for combination products, the potential effects of which in terms of approval and timing could independently affect our ability to market our combination products in the EU.

While we intend to seek designations for our product candidates with the FDA and comparable other regulatory authorities that are intended to confer benefits such as a faster development process or an accelerated regulatory pathway, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The FDA and comparable other regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review. Despite these designations, there can be no assurance that we will successfully obtain these or other designations for any of our other product candidates. In addition, while such designations could expedite the development or review process, they generally do not change the standards for approval. Even if we obtain such designations for one or more of our product candidates, there can be no assurance that we will realize their intended benefits.

For example, we have received a Breakthrough Therapy designation for EFX for the treatment of MASH and we may seek a Breakthrough Therapy designation for some of our product candidates in the future. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in control regimens. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product

candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for designation.

In addition, in October 2021, the FDA granted Fast Track designation for EFX for the treatment of MASH, and we may seek Fast Track designation for some of our future product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track Designation, as we have for EFX for the treatment of MASH, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track Designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

Biologics designated as breakthrough therapies or granted Fast Track designation by the FDA may also be eligible for other expedited approval programs, including accelerated approval. A product candidate may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of accelerated approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is permitted to require that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. In addition, FDORA gives the FDA increased authority to withdraw accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. The FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. Accelerated approval may also be withdrawn if, among other things, a confirmatory trial required to verify the predicted clinical benefit of the product fails to verify such benefit or if such trial is not conducted with due diligence. In addition, the FDA generally requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to full marketing approval.

We may seek priority review designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not result in expedited development and does not necessarily result in expedited regulatory review or approval process or necessarily confer any advantage with respect to

approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing EFX or any future product candidates outside the United States.

We intend to market any approved products in the United States, the European Union, Japan and other foreign jurisdictions. Even if our products are approved for marketing in the United States, in order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country. For example, even if EFX is approved in the United States, the EMA may require more information, including additional nonclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans in the European Union. Moreover, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others.

Also, regulatory approval for our product candidate or any future product candidates may be withdrawn if we fail to comply with regulatory requirements, if problems occur after the product candidate reaches the market or for other reasons. If we fail to comply with the regulatory requirements in international markets and fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidate or any future product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we fail to obtain approval of our product candidate or any future product candidates by regulatory authorities in another country, we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline.

Risks Related to Ongoing Regulatory Obligations

Even if we are able to obtain regulatory approvals for our product candidate or any future product candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

Clinical trials are conducted in representative samples of the potential patient population which may have significant variability. Even if we receive regulatory approval for EFX or any of our future product candidates, we will have tested them in only a small number of patients during our clinical trials. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of our product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to the product candidate for a longer duration, may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such studies may not be sufficient to identify when those events may occur. If our applications for marketing are approved and more patients begin to use our product, new risks and side effects associated with our products may be discovered. There have been other products that have been approved by the regulatory authorities but for which safety concerns have been uncovered following approval. Such safety concerns have led to labelling changes or withdrawal of products from the market, and any of our product candidates may be subject to similar risks. Additionally, we may be required to conduct additional nonclinical and clinical trials, require additional warnings on the label of our product candidate, reformulate our product or make changes, create a medication guide outlining the risks of such side effects for distribution to patients and obtain new approvals for our and our suppliers' manufacturing facilities for EFX and any future product candidates. We might have

to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our product if and when regulatory approvals for such product are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

Even if our current product candidate or any future product candidates receive regulatory approval, they will remain subject to extensive regulatory scrutiny and may still face future development and regulatory difficulties.

Even if we obtained regulatory approval for a product candidate, regulatory authorities may still impose significant restrictions on our product candidates, including their indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies. For example, if EFX is approved by the FDA based on a surrogate endpoint pursuant to accelerated approval regulations (also referred to as Subpart E regulations), we will be required to conduct additional confirmatory clinical trials demonstrating the clinical benefit on the ultimate outcome of MASH. Further, even if we obtained regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information.

The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of our product candidate or any future product candidates, they may require labeling changes or establishment of a risk evaluation and mitigation strategy or similar strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of our products, if approved, and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP and applicable QSRs, regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, EFX, or any future product candidates or the manufacturing facilities for EFX, the delivery device used for EFX, or any future product candidates fail to comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, a regulatory agency may:

- issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- mandate modifications to instructions for use;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require that we conduct post-marketing studies;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend marketing of, withdraw regulatory approval of or recall such product;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' ("HHS") Office of Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the government. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these federal False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses involving fines in excess of $1 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidate or any future product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Risks Related to Healthcare Regulation

The advancement of healthcare reform may negatively impact our ability to profitably sell our product candidate or any future product candidates, if approved.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidate or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. For more information on healthcare laws and regulations that may impact our company, see the section titled "Business—Government regulation—Healthcare reform" included in our Annual Report on Form 10-K for the year ended December 31, 2024.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act" or "ACA"), was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive

Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Trump Administration or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. The U.S. Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2031 unless Congress takes additional action. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Centers for Medicare & Medicaid Services ("CMS") has published a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

In addition, at a federal level, President Trump reversed some of President Biden's executive orders including rescinding Executive Order 14087 entitled "Lowering Prescription Drug Costs for Americans". President Trump may issue new executive orders designed to impact drug pricing. A number of these and other proposed measures may require authorization through additional legislation to become effective. Congress and the Trump administration have indicated that they will continue to seek new legislative measures to control drug costs.

In August 2022, the IRA was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay until January 1, 2032 the implementation of the HHS rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. Further, under the IRA, orphan drugs were previously exempted from the Medicare drug price negotiation program, however, this exemption was restricted to drugs with only one orphan designation and for which the only approved indication is for that disease or condition. If a product received multiple orphan designations or had multiple approved indications, it would not qualify for the orphan drug exemption. Under the OBBBA, this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan designations or indications, are exempt from the Medicare drug price negotiation program. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effect of the IRA on our business and the healthcare industry in general is not yet known.

On April 15, 2025, the Trump Administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called "pill penalty" under the Inflation Reduction Act that creates a distinction between small molecule and large molecule products for purposes of determining when a drug may be eligible for drug price negotiation. On May 12, 2025, the Trump Administration published Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" which generally, among other things, directs the federal government to establish and communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the Administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should

manufacturers fail to offer American consumers the most-favored-nation lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Notably, a similar "Most Favored Nation" pricing rule enacted under the first Trump Administration was subject to an injunction resulting from judicial challenges to the rule, which was formally rescinded by the former Biden Administration in August 2021.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our approved products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. Although a number of these, and other proposed measures may require additional authorization to become effective, and the Trump Administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payors.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, and if approved, market, sell and distribute our products. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program, such as Medicare and

Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which can be enforced through civil whistleblower or *qui tam* actions, prohibit individuals or entities from, among other things knowingly presenting, or causing to be presented, to the federal government or a government contractor, grantee, or other recipient of federal funds, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; knowingly making, using or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense or knowingly and willfully making false statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their implementing regulations, including the Final Omnibus Rule published in January 2013, imposes obligations on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their business associates, which are individuals and entities that perform certain services involving the creation, maintenance, receipt, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal Open Payments program, created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians (as defined above) and their immediate family members. As of January 1, 2022, these reporting obligations have now extended to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners; and

- analogous state, local, and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug prices; state and local laws that require the registration of pharmaceutical sales representatives; several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the EU General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Failure to comply with health, data protection, and national security laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection and national security laws and regulations (i.e., laws and regulations that address privacy, data security, and national security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and the CCPA, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. The CCPA and similar consumer privacy laws in other states provide a comprehensive privacy framework for covered businesses by creating a broad definition of personal information, establishing data privacy rights for consumers, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA and other state consumer privacy laws may impact some of our business activities.

States are continuing to propose new privacy laws, some of which are similar to the above discussed recently passed laws and other proposals differ dramatically. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. There are also states that are specifically regulating health information. For example, Washington's WA MHMDA applies robust protections similar to, or more stringent than, the requirements of the CCPA, for the collection, use, and disclosure of consumer health data. The WA MHMDA provides a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have

also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted. In addition, the federal government has begun to regulate certain disclosures of personal information under national security and trade regulation frameworks. For example, Executive Order 14117 on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern, as implemented by Department of Justice regulations issued in December 2024, prohibits certain transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict investment agreements, employment agreements and vendor agreements involving such data and countries of concern. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions, and may result in exclusion from participation in federal and state programs.

Compliance with U.S. and international data protection laws and regulations, including the General Data Protection Regulation ("GDPR") and other European Economic Area ("EEA") and United Kingdom ("UK") data protection laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Where we collect and otherwise process personal data regarding Europe, including in the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials, we may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data regarding (i) individuals in the EEA and UK and/or (ii) carried out in the context of the activities of an establishment in the EEA and UK, is subject to the EU General Data Protection Regulation ("EU GDPR"), and similarly, processing of personal data regarding individuals in the UK is subject to the GDPR, as well as other supplementary national data protection legislation in force in the EEA member states and the UK (including the UK Data Protection Act 2018). The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements related to having a legal basis for processing personal data, stricter requirements related to processing of sensitive data (including health data), obtaining consent of the individuals to whom the personal data relates or ensuring another appropriate legal basis or condition applies to the processing of personal data, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, requiring data protection impact assessments for high risk processing and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA/UK, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million (£17.5 million under UK GDPR) or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers of personal data to countries outside the EEA/UK that are not considered by the European Commission and UK government as providing "adequate" protection to personal data ("third countries"), including the United States. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or

require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards (for example, the European Commission approved Standard Contractual Clauses ("SCCs")) must be implemented in compliance with European and UK data protection laws. In addition, transfers made pursuant to the SCCs (and other similar appropriate transfer safeguards) need to be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular regarding applicable surveillance laws and relevant rights of individuals with respect to the transferred personal data, to ensure an "essentially equivalent" level of protection to that guaranteed in the EEA in the jurisdiction where the data imported is based ("Transfer Impact Assessment"). On June 4, 2021, the EC issued forms of standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA. The UK is not subject to the EC's standard contractual clauses but has published its own transfer mechanism, the International Data Transfer Agreement and International Data Transfer Addendum, which will enable transfers from the UK, and has also implemented a similar Transfer Impact Assessment requirement. Further, the European Union and United States have adopted its adequacy decision for the EU-U.S. Data Privacy Framework ("Framework"), which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the European Union and the United States is comparable to that offered in the European Union. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks. We will be required to implement these new safeguards and carry out Transfer Impact Assessments when conducting restricted data transfers under the GDPR and doing so will require significant effort and cost, and may result in us needing to make strategic considerations around where EEA or UK personal data is stored and transferred, and which service providers we can utilize for the processing of EEA/UK personal data.

Although the UK is regarded as a third country under the EU GDPR, the European Commission has issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The UK Government has also now introduced a Data Protection and Digital Information Bill into the UK legislative process which will introduce changes to the UK GDPR. This may lead to additional compliance costs and could increase our overall risk. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of European personal data and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EEA. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties.

In addition, EEA Member States have adopted national laws to implement the EU GDPR that may partially deviate from the EU GDPR and competent authorities in the EEA Member States may interpret the EU GDPR obligations slightly differently from country to country. Therefore, we do not expect to operate in a uniform legal landscape in the EEA.

Compliance with the above and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, reputation, financial condition and results of operations.

Artificial intelligence presents risks and challenges that can impact our business, including by posing security risks to our confidential information, proprietary information and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may

adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security.

A growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of artificial intelligence, and use of such technologies in compliance with ethical standards and societal expectations. For example, the EU's Artificial Intelligence Act ("AI Act") imposes significant obligations on providers and deployers of artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. Likewise, in the U.S., several states, including Colorado and California, passed laws to regulate various uses of artificial intelligence, including to make consequential decisions. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of artificial intelligence in regulated sectors. The FDA, for example, issued guidance on the use of artificial intelligence in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use artificial intelligence systems governed by these laws or regulations, we will need to apply significant resources to design, develop, test and maintain such systems in accordance with applicable law and regulation, with the potential for significant enforcement or litigation in the event of any perceived non-compliance.

Our vendors may also incorporate generative artificial intelligence tools into their offerings and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available procedures. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Healthcare insurance coverage and reimbursement may be limited or unavailable for our product candidate, if approved, which could make it difficult for us to sell our product candidate or other therapies profitably.

The success of our product candidate, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, commercial payors, and health maintenance organizations. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop. For more information on healthcare laws and

regulations that may impact our company, see the section titled "Business—Government regulation—Coverage, pricing, and reimbursement" included in our Annual Report on Form 10-K for the year ended December 31, 2024.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from third-party payors are critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a third-party payor is a time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private third-party payors tend to follow Medicare coverage and reimbursement limitations to a substantial degree, but also have their own methods and approval process apart from Medicare determinations. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Our activities in the United States subject us to various laws relating to foreign investment and the export of certain technologies, and our failure to comply with these laws or adequately monitor the compliance of our suppliers and others we do business with could subject us to substantial fines, penalties and even injunctions, the imposition of which on us could have a material adverse effect on the success of our business.

Because we have substantial operations in the United States, we are subject to U.S. laws that regulate foreign investments in U.S. businesses and access by foreign persons to technology developed and produced in the United States. These laws include Section 721 of the Defense Production Act of 1950, as amended by the Foreign Investment Risk Review Modernization Act of 2018, and the regulations at 31 C.F.R. Parts 800 and 801, as amended, administered by the Committee on Foreign Investment in the United States; and the Export Control Reform Act of 2018, which is being implemented in part through Commerce Department rulemakings to impose new export control restrictions on "emerging and foundational technologies" yet to be fully identified. Application of these laws, including as they are implemented through regulations being developed, may negatively impact our business in various ways, including by

restricting our access to capital and markets; limiting the collaborations we may pursue; regulating the export our products, services, and technology from the United States and abroad; increasing our costs and the time necessary to obtain required authorizations and to ensure compliance; and threatening monetary fines and other penalties if we do not.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key personnel, and substantial changes in leadership, personnel, and policy could prevent new or existing product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including substantial leadership, personnel, and policy changes, may also slow the time necessary for new drug candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In September 2025, Congress failed to enact a budget for the upcoming fiscal year, which resulted in a partial government shutdown that began on October 1, 2025, and remains in effect as of the date of this report. The current U.S. government shutdown impacts several regulatory agencies, such as the FDA and the SEC, which have furloughed critical government employees and stopped critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, the current and future government shutdowns or substantial leadership, personnel, and policy changes could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception and we expect to incur losses for the foreseeable future.

We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant losses in each period since our inception in January 2017. For the nine months ended September 30, 2025 and 2024, we reported net losses of $222.8 million and $182.0 million, respectively. For the years ended December 31, 2024 and 2023, we reported net losses of $252.1 million and $151.8 million, respectively. As of September 30, 2025, we had an accumulated deficit of $1,049.0 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidate. We anticipate that our expenses will increase substantially if, and as, we:

- continue large-scale clinical trials for our product candidate, EFX, and any future product candidates;
- discover and develop new product candidates, and conduct nonclinical studies and clinical trials;
- incur any disruption or delays to the supply of our product candidate;
- manufacture, or have manufactured, clinical and commercial supplies of our product candidates;
- seek regulatory approvals for EFX or any future product candidates;
- commercialize EFX or any future product candidates, if approved;
- attempt to transition from a company with a development focus to a company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- hire additional clinical, scientific, and management personnel;
- add operational, financial, and management information systems and personnel;
- identify additional compounds or product candidates and acquire rights from third parties to those compounds or product candidates through licenses; and
- incur additional costs associated with operating as a public company.

Even if we succeed in commercializing EFX or any future product candidates, we may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We currently have a limited operating history, have not generated any revenue to date, and may never become profitable.

We are a clinical-stage biotechnology company with a limited operating history. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology and product candidate, EFX, and conducting nonclinical studies and clinical trials of EFX. We have not yet demonstrated our ability to complete late-stage clinical trials, obtain regulatory approval, formulate and manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful product commercialization. Investment in biotechnology product development is highly speculative because it entails substantial upfront expenditures in clinical research organizations and contract manufacturing organizations and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Though Phase 3 clinical development of EFX has been initiated, we do not expect to receive revenue from EFX for a number of years, if ever. To date, we have not generated any revenue and we will not be able to generate product revenue unless and until EFX, or any future product candidate, successfully completes clinical trials, receives regulatory approval, and is commercialized. We may seek to obtain revenue from collaboration or licensing agreements with third parties. Our ability to generate future product revenue from EFX or any future product candidates also depends on a number of additional factors, including our, or our current and future contractors' and collaborators', ability to:

- successfully complete nonclinical studies and clinical trials for EFX and any future product candidates;
- seek and obtain marketing approvals for any product candidates that complete clinical development;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- launch and commercialize any product candidates for which we obtain marketing approval, and, if launched independently, successfully establish a sales, marketing and distribution infrastructure;

- demonstrate the necessary safety data post-approval to ensure continued regulatory approval;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- achieve market acceptance for any approved products;
- address any competing technological and market developments;
- maintain our rights under our existing license agreement with Amgen and any similar agreements we may enter into in the future;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter in the future and performing our obligations in such collaborations;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with biotechnology product development, including that our product candidate may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or foreign regulatory authorities, to perform nonclinical studies or clinical trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing any approved product.

If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

If the Merger is not consummated, we will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of our product candidate or develop any future product candidates.

As a research and development company, our operations have consumed substantial amounts of cash since inception. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance EFX into later-stage clinical development.

As of September 30, 2025, we had $988.3 million of cash, cash equivalents and short-term and long-term marketable securities. Since our IPO in June 2019, we have raised capital primarily through the sale of our common stock in follow-on public offerings, registered direct offerings and ATM offerings. In January 2025, we raised gross proceeds of $402.5 million from a follow-on public offering of our common stock and pre-funded warrants and $10.6 million through the sale of common stock under an ATM offering. We also borrowed $35.0 million cumulatively under a Term Loan facility provided by Hercules, which has been repaid. From our inception through September 30, 2025, these and other funding sources have provided gross proceeds totaling $1,910.4 million. Any forecast of the period of time through which our financial resources will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. The assumptions underlying any estimate may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both short and long-term, will depend on many factors, including, but not limited to:

- if and when the proposed Merger with Novo is consummated;
- the initiation, progress, timing, costs and results of nonclinical studies and clinical trials for our product candidate or any future product candidates we may develop;
- the cost and timing of manufacturing our product candidate for use in clinical trials or, if approved by the FDA, for commercial use;
- our ability to maintain our license to EFX from Amgen;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;

- the effect of competing technological and market developments;
- market acceptance of any approved product candidates, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial scale manufacturing;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, and if the Merger is not consummated, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we could be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for one or more of our current or any future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. If the Merger is not consummated and we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Risks Related to Commercialization and Market Acceptance

Risks Related to Commercialization

Even if we commercialize EFX or any future product candidates, if approved, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidate or any future product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors determine which medications they will cover and establish reimbursement levels. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party

payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval, if any. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which marketing approval is obtained, if any.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize future product candidates, and our ability to generate revenue will be materially impaired.

We could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*., which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act (APA). Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. Another decision, *Securities and Exchange Commission v. Jarkesy*, overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Further, our ability to develop and market new drug products may be impacted by litigation challenging the FDA's approval of another company's drug product. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product originally approved in 2000 whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed that decision after unanimously finding that the plaintiffs (anti-abortion doctors and organizations) did not have standing to bring this legal action against the FDA. On October 11, 2024, the Attorneys General of three states (Missouri, Idaho and Kansas) filed an amended complaint in the district court in Texas challenging FDA's actions. On January 16, 2025, the district court agreed to allow these states to file an amended complaint and continue to pursue this challenge. Depending on the outcome of this litigation, our ability to develop new drug product candidates and to maintain approval of existing drug products could be delayed, undermined or subject to protracted litigation.

Finally, with the change in presidential administrations in 2025, there is substantial uncertainty as to how the new administration will modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and could materially adversely impact our business and prospects.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidate or any future product candidates in human clinical trials and will face an even greater risk if we commercialize any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, their family members, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidate or any future product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize any products that we may develop; and
- a decline in our stock price.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidate or any future product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician adoption of our product or expand our business.

Risks Related to Market Acceptance

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not currently have an infrastructure for the sales, marketing, and distribution of pharmaceutical products. In order to market our product candidates, if approved by the FDA or any other regulatory body, we must build our sales, marketing, managerial, and other non-technical capabilities, or make arrangements with third parties to perform these services. There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively and they could expose our company to regulatory enforcement and

legal risk in the execution of their sales and commercialization activities. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved.

If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition, and prospects will be materially adversely affected.

Our product candidate or any future product candidates may not achieve adequate market acceptance among physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if our product candidate or any future product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors, pharmaceutical companies and others in the medical community. Demonstrating the safety and efficacy of our product candidate or any future product candidates and obtaining regulatory approvals will not guarantee future revenue. Our commercial success also depends on coverage and adequate reimbursement of our product candidate or any future product candidates by third-party payors, including government payors and private insurers, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. Third-party payors closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that will apply. We cannot be certain that third-party payors will sufficiently reimburse sales of our product or enable us to sell our product at a profitable price. Similar concerns could also limit the reimbursement amounts that health insurers or government agencies in other countries are prepared to pay for our products. In many regions, including Europe, Japan and Canada, where we may market our products, the pricing of prescription drugs is controlled by the government or regulatory agencies. Regulatory agencies in these countries could determine that the pricing for our products should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market our products at a premium as new drugs. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile of the product candidate as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by clinics and patients;
- the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors;
- the relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to our product candidate or any future product candidates.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate

level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Risks Related to Our Operations

We incur significant costs and expend significant time and effort, as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices.

We incur significant legal, accounting and other expenses, and expend significant time and effort by management and other personnel, to comply with the rules applicable to us as a public company. We are subject to the reporting requirements of Nasdaq and of the Exchange Act, which require, among other things, that we file with the SEC, annual, quarterly, and current reports with respect to our business and financial condition and that we establish and maintain effective disclosure controls, procedures and corporate governance practices. We must also comply with the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), and specifically Section 404 of the Sarbanes-Oxley Act, which requires that we establish and maintain effective internal controls over financial reporting. In order to maintain compliance with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting, to certify financial and other information in our quarterly and annual reports and to provide an annual management report on the effectiveness of our internal control over financial reporting, which includes the disclosure of any material weaknesses and associated remediation activities. Also, as a large accelerated filer, we incur additional significant costs to meet the requirement to provide an attestation report on our internal control over financial reporting from our independent registered public accounting firm. We will need to continue to dedicate significant internal resources and outside consultants in order to complete management's annual assessment and to prepare for when we are no longer a smaller reporting company. Despite these efforts, there is no guarantee that we will be able to conclude that our internal controls over financial reporting remain effective.

Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies, and the additional compliance requirements that we will be subject to when we are no longer a smaller reporting company, to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain key financial or management personnel.

If we fail to maintain an effective system of internal controls over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior

internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our stock.

If material weaknesses or significant deficiencies in our internal control over financial reporting are identified in the future, we may not detect or remediate errors on a timely basis and our condensed consolidated financial statements may be materially misstated. We, or our independent registered public accounting firm, may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from Nasdaq or other adverse consequences that would materially harm our business.

If our information technology systems or those of third parties upon which we rely, or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm and other adverse consequences.

We, like other organizations in our industry, have experienced and expect to continue to experience cyber threats and incidents. We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, attacks enhanced or facilitated by AI, and other similar threats. These threats are growing in complexity and frequency, making them increasingly difficult to detect and address, potentially leading to data loss, operational interruptions, reputational harm, and financial losses.

Our operations depend heavily on third-party service providers for critical functions, including cloud-based infrastructure, data centers, encryption and authentication technologies, employee email, clinical research and development, manufacturing, and other functions. We have limited control over these providers' security practices, and they may not have adequate information security measures in place. Consequently, a security incident affecting our providers could severely impact our operations and reputation. While we may be entitled to damages if our third-party service providers fail to satisfy their data privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Security incidents could result in unauthorized access to sensitive information, data loss or corruption, operational disruptions, and increased costs and efforts to recover data. They may also lead to regulatory fines and legal liabilities. Despite our implementation of security measures, no system is entirely secure. We cannot guarantee that our efforts will detect all vulnerabilities or prevent all incidents. Our preventative measures include monitoring and updating security protocols. The potential financial impact of these incidents, including increased costs and potential legal liabilities, is a significant concern.

For example, the loss of clinical trial data from completed or future clinical trials could have significant implications. It could lead to delays in regulatory approval efforts, necessitating costly remediation measures such as liability for stolen assets or information, repairs to damaged systems, and incentives to maintain relationships with business partners post-attack. Moreover, investigation costs may arise, including expenses related to notifying data subjects, regulators, or others, as well as engaging third-party forensic investigators and experts. This could further entail increased expenditures on cybersecurity protections, such as organizational changes, additional personnel, advanced technologies, employee training, and consultations with external experts. Additionally, higher insurance premiums might be incurred, while reputational damage could undermine customer and investor confidence, impacting the company's

competitiveness, stock price, and long-term shareholder value. Lastly, there could be substantial costs associated with recovering or reproducing the lost data.

Certain data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure, or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

We use and generate materials that may expose us to material liability.

Our research programs involve the use of hazardous materials and chemicals, which are currently only handled by third parties. We are subject to foreign, federal, state and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products. We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers' compensation, property and business interruption insurance and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

General Risk Factors

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by economic and political changes in the location in which we, or our suppliers and vendors, maintain operations. For example, our business may be generally exposed to the impact of political or civil unrest or military action. While we do not have direct exposure to Ukraine or Russia, we do have third-party manufacturing partners with locations in Europe, which may be affected by the ongoing conflict between Russia and Ukraine. In addition, we have activated sites for our SYNCHRONY trials in India, Israel and Turkey. These sites may be materially impacted or delayed by the increasing conflict in the Middle East, including between India and Pakistan, and could result in difficulties screening and enrolling patients in such areas on schedule. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our business is affected by macroeconomic conditions, including rising inflation, interest rates, supply chain constraints and significant political, trade, or regulatory developments.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. For instance, rising interest rates have impacted the Company's net income. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on the Company's product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new therapeutic

products may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third-party suppliers and manufacturers to manufacture clinical trial materials for our product candidates.

Additionally, significant political, trade, or regulatory developments, such as those stemming from the change in U.S. federal administration, are difficult to predict and could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, in early 2025, the U.S. imposed tariffs on imports from Canada and Mexico, the EU and China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. While certain tariffs have been suspended, modified or temporarily reduced, we cannot predict the results of the U.S. government's trade negotiations or the outcome of ongoing legal challenges to specific tariff policies. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, in jurisdictions where our third-party suppliers and manufacturers operate, could have a material adverse effect on our financial condition or results of operations.

On September 25, 2025, the current U.S. administration announced a 100% tariff on brand-name or patented drugs unless pharmaceutical companies expand their manufacturing operations in the U.S. While pharmaceutical products are currently excluded from the baseline and "reciprocal" tariffs imposed by the U.S., such tariffs still apply to raw materials or other products necessary for the manufacture and formulation of our marketed products and product candidates, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties or our collaborators to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of our marketed products and product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contaminations, business interruptions, or labor shortages or disputes (in each case, including as a result of the armed conflict between Russia and Ukraine or public health outbreaks, epidemics, or pandemics or other geopolitical developments). Regional or single-source dependencies may in some cases accentuate these risks. For example, the pharmaceutical industry generally, and in some instances our Company or our collaborators or other third parties on which we rely, depend on China-based suppliers or service providers for certain raw materials, products and services, or other activities. Our ability or the ability of our collaborators or such other third parties to continue to engage these China-based suppliers or service providers for certain preclinical research programs and clinical development programs could be restricted due to geopolitical developments between the United States and China, including as a result of the escalation of tariffs or other trade restrictions or if the previously proposed federal legislation known as the BIOSECURE Act or a similar law were to be enacted. In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. This, in turn, could materially and adversely affect our or our collaborators' ability to manufacture or supply marketed products and product candidates or advance our or our collaborators' preclinical research or clinical development programs, which could materially and adversely affect our business and future prospects.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the

ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry.

We are a "large accelerated filer" as defined by the SEC, and the reduced disclosure requirements previously available to us no longer apply.

As of June 30, 2024, the market value of our common stock that was held by non-affiliates exceeded $700 million, and as a result, we continue to qualify as a "large accelerated filer". As such, we incur significant additional expenses in complying with the Sarbanes-Oxley Act and rules implemented by the SEC. As a large accelerated filer, we are subject to certain disclosure requirements that are applicable to other public companies that were not applicable to us as a smaller reporting company. These requirements include:

- compliance with the auditor attestation requirements of Section 404;
- compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- full disclosure obligations regarding executive compensation; and
- compliance with the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

If we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Risks Related to an Investment in Our Securities

The market price of our stock may be volatile, and you could lose all or part of your investment. Because of potential volatility in our trading price and trading volume, we may incur significant costs from class action securities litigation.

The trading price of our common stock is likely to be volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. For example, between January 1, 2024 and September 30, 2025, our stock price has ranged from $15.32 to $58.40. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- developments associated with our license with Amgen, including any termination or other change in our relationship with Amgen;
- the success of competitive products or technologies;
- regulatory actions with respect to our product candidate or any future product candidates or our competitors' product candidates or products;
- results of clinical trials of our product candidate or any future product candidates or those of our competitors;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors or collaborators of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- regulatory, legal or payor developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidate or any future product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;

- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- general economic, industry and market conditions;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad (such as the ongoing conflict between Ukraine and Russia, including the sanctions imposed by the United States, the European Union and others on Russia and other related parties);
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Although the markets recovered, market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to inflation, rising interest rates, may significantly reduce the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and material adverse impact on the market price of our common stock.

Holders of stock in companies that have a volatile stock price frequently bring securities class action litigation against the company that issued the stock. We have been and may in the future be the target of this type of litigation. The outcome of such pending and potential litigation is uncertain. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. Although the results of lawsuits and claims cannot be predicted with certainty, defending against such claims could be costly and divert our management's attention from other business concerns, which could seriously harm our business. Any litigation to which we become a party may result in an onerous or unfavorable judgment, or may be resolved with a monetary payment.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company or if they cease to cover our company, the trading price for our stock would likely be negatively impacted. In the event that securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these

analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Risks Related to Our Charter and Bylaws

Anti-takeover provisions under our organizational documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our fourth amended and restated certificate of incorporation and second amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of the stockholders may be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office, and special meetings of stockholders may not be called by any other person or persons;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds (2/3) of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than a majority of all outstanding shares of our voting stock to amend any bylaws by stockholder action and not less than two-thirds (2/3) of all outstanding shares of our voting stock to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our fourth amended and restated certificate of incorporation and second amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware (or, if such court does not have jurisdiction thereof, another state court or a federal district court located within the State of Delaware) will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our second amended and restated bylaws (including the interpretation, validity or enforceability thereof), or (iv) any action asserting a claim that is governed by the internal affairs doctrine (the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under

the Securities Act (the "Federal Forum Provision"). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Risks Related to Income Taxes

Changes in tax laws could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2024, we had U.S. federal and state net operating loss, or NOL, carryforwards of $333.0 million and $660.8 million, respectively and federal and state research and development tax credit carryforwards of $26.4 million and $3.4 million, respectively. If not utilized, such NOL carryforwards (other than federal NOL carryforwards arising in taxable years beginning after December 31, 2017) and research and development credits will expire at various dates beginning in 2033. Our ability to use our U.S. federal and state NOL and tax credit carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. These NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the current law, federal NOL carryforwards generated in tax years beginning after December 31, 2017, are not subject to expiration. However, any such NOL carryforwards may only offset 80% of our annual taxable income in taxable years beginning after December 31, 2020. In addition, under Sections 382 and 383 of the Code, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50 percentage points by certain stockholders, as interpreted by the U.S. Internal Revenue Service, over a three-year period. We experienced such ownership changes on March 24, 2017, June 7, 2018, July 8, 2020, and May 31, 2024. We may experience ownership changes again in the future, some of which may be outside our control. No ownership change occurred in 2022 or 2023. As a result, our use of federal NOL and tax credit carryforwards could be limited. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial position and cash flows.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

During the nine months ended September 30, 2025, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Form 10-K.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

The following table describes contracts, instructions or written plans for the sale or purchase of our securities adopted by our directors and certain officers during the quarter ended September 30, 2025, each of which is intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5-1(c), referred to as Rule 10b5-1 trading plans.

Name and Title	Date and Action Taken	Duration of Trading Arrangement	Aggregate Number of Securities to be Sold or Purchased
William White, Chief Financial Officer and Head of Corporate Development	Plan Adopted on August 12, 2025	182 Days	168,087
Scott Gangloff, Chief Technical Officer	Plan Adopted on August 21, 2025	182 Days	4,789
Catriona Yale, Chief Development Officer	Plan Adopted on August 26, 2025	217 Days	150,038
Patrick Lamy, Senior Vice President of Commercial Strategy	Plan Adopted on September 5, 2025	356 Days	36,204

Other than as disclosed above, no director or officer (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as defined in Item 408 of Regulation S-K) during the quarter ended September 30, 2025.

Table of Contents

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit Number	Exhibit Description
2.1	Agreement and Plan of Merger, dated as of October 9, 2025, by and among Akero Therapeutics, Inc., Novo Nordisk A/S and NN Invest Sub, Inc (incorporated by reference to Exhibit 2.1 of the Registrant's Current Report on Form 8-K (File No. 001-38944) filed on October 9, 2025)
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38944) filed on June 24, 2019)
3.2	Amended and Restated Bylaws of the Registrant and the amendments thereto (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-38944) filed on March 12, 2021)
3.3	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38944) filed on June 12, 2024)
3.4	Amendment to the Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38944) filed on October 9, 2025)
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended
32.1+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase documents
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

\+ The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

SIGNATURES

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

AKERO THERAPEUTICS, INC.

Date: November 7, 2025 By: /s/ ANDREW CHENG

Andrew Cheng, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2025 By: /s/ WILLIAM WHITE

William White
Executive Vice President, Chief Financial Officer and
Head of Corporate Development
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Cheng, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Akero Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2025

/s/ ANDREW CHENG
Andrew Cheng, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, William White, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Akero Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2025

/s/ WILLIAM WHITE
William White
Executive Vice President, Chief Financial Officer and Head of Corporate Development
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Cheng, certify pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Akero Therapeutics, Inc. for the quarterly period ended September 30, 2025, fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act and that the information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and result of operations of Akero Therapeutics, Inc.

Dated: November 7, 2025

/s/ ANDREW CHENG
Andrew Cheng, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

I, William White, certify pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Akero Therapeutics, Inc. for the quarterly period ended September 30, 2025, fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act and that the information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and result of operations of Akero Therapeutics, Inc.

Dated: November 7, 2025

/s/ WILLIAM WHITE
William White
Executive Vice President, Chief Financial Officer and Head of Corporate Development
(Principal Financial and Accounting Officer)