UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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, 2026

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 Number: 001-40969

ENTRADA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**81-3983399**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
One Design Center Place	
Suite 17-500	
Boston, MA	**02210**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (857) 520-9158

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	**TRDA**	**The Nasdaq Global 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 October 31, 2026, the registrant had 39,150,334 shares of common stock, $0.0001 par value per share, outstanding.

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We own various U.S. federal trademark applications and unregistered trademarks, including our company name and logo, that we use in connection with the operation of our business. This Quarterly Report on Form 10-Q ("Quarterly Report") may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties' trademarks, service marks, trade names or products in this Quarterly Report is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this Quarterly Report may appear without the ®, TM or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner of these trademarks, service marks and trade names will not assert, to the fullest extent under applicable law, its rights.

From time to time, we may use our website or our LinkedIn profile at www.linkedin.com/company/entradatx to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors Relations section of our website, available at www.entradatx.com. Investors are encouraged to review the Investors Relations section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website or our LinkedIn profile is not incorporated into, and does not form a part of, this Quarterly Report.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Quarterly Report") contains express or implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements are based on our management's current beliefs, expectations and assumptions about future events, conditions and results and on information currently available to us.

These statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about:

- the initiation, timing, progress, results and costs of conducting our research and development programs, our current and future preclinical studies, and our current and future 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 current and future programs;
- the ability of our preclinical studies and clinical trials to demonstrate safety and efficacy of our therapeutic candidates, and other positive results;
- the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of our therapeutic candidates;
- substantial doubt regarding our ability to continue as a going concern and our need to raise capital in the near term in order to maintain our operations;
- the timing, scope and likelihood of regulatory filings and approvals, including timing of any Investigational New Drug application ("IND") and final U.S. Food and Drug Administration ("FDA") or foreign equivalent approval of our current therapeutic candidates or any future therapeutic candidates;
- the timing or content of any update regarding our regulatory filings;
- the ability to leverage our proprietary EEV platform ("EEV Platform") to efficiently develop additional therapeutic candidates, including by applying learnings from one program to other programs and from one indication to our other indications;
- our estimates of the number of patients that we will enroll and our ability to initiate, recruit and enroll patients in and conduct and successfully complete clinical trials at the pace that we project;
- the costs of manufacturing and our ability to scale-up our manufacturing and processing approaches to appropriately address our anticipated commercial needs, which will require significant resources;
- our ability to establish or maintain collaborations or strategic relationships and the ability and willingness of our third-party strategic collaborators to undertake research and development activities relating to our current or future therapeutic candidates and discovery programs;
- our expectations regarding the potential benefits of the partnership, licensing and/or collaboration arrangements and other strategic arrangements and transactions we have entered into or may enter into in the future;
- the potential benefits of our technologies and programs, including those with strategic partners;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our therapeutic candidates;
- our ability to take advantage of expedited regulatory pathways for our therapeutic candidates;
- our ability to obtain and maintain regulatory approval of our therapeutic candidates;
- the implementation of our business model, and strategic plans for our business, therapeutic candidates, and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and other therapeutic candidates we may develop, including the extensions of existing patent terms where available, and the validity of intellectual property;
- rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- the period over which we estimate our available financial resources, together with ongoing research support will enable us to fund the Company's current and future operating expenses and capital expenditure requirements;

- our financial performance and estimates of our future expenses, revenues, capital requirements, use of our cash reserves, and our needs for additional financing;
- future agreements with third parties in connection with the development and commercialization of our therapeutic candidates and any other approved product;
- the rate and degree of market acceptance and the size and growth potential of the markets for our therapeutic candidates, and our ability to serve those markets;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to produce our therapeutic candidates with advantages in turnaround times or manufacturing cost;
- our competitive position and the success of competing therapies that are or may become available;
- our need for and ability to attract and retain key scientific, management and other personnel and to identify, hire and retain additional qualified professionals;
- our anticipated use of our existing resources;
- the expected timing, progress and success of our collaboration with Vertex Pharmaceuticals Incorporated ("Vertex"), including any future payments we may receive under our collaboration and license agreements, as well as our ability to identify and enter into future license agreements and collaborations;
- our beliefs and expectations regarding milestone, royalty or other payments that could be due to third parties under existing agreements;
- the impact of macroeconomic and geopolitical developments on our business, including inflationary pressures and capital market disruptions, changes in or disruptions of U.S. governmental agencies, whether from a U.S. federal government shutdown or reduced resources, new or increased international tariffs and retaliatory tariffs, trade protection measures, military conflicts, such as the recent conflict in Iran and ongoing conflicts in Ukraine and the Middle East, economic sanctions and economic slowdowns or recessions that may result from such developments which could harm our research and development efforts as well as the value of our common stock and our ability to access capital markets;
- other risks and uncertainties, including those listed under the caption "Risk Factors."

In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target," "contemplate," "possible," "can," or the negative of these terms or other comparable terminology, and similar expressions, although not all forward-looking statements contain these identifying words. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled "Risk Factors" and elsewhere in this Quarterly Report. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report and the documents that we reference in this Quarterly Report and have filed with the Securities and Exchange Commission thereto completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Quarterly Report represent our views as of the date of this Quarterly Report. We do not undertake any obligation to publicly update any forward-looking statement except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report.

This Quarterly Report also contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. All of the market data used in this Quarterly Report involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our

estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research, and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

This Quarterly Report contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed as exhibits to this Quarterly Report. Unless the context otherwise requires, reference in this Quarterly Report to the terms "Entrada," "Entrada Therapeutics," "the Company," "we," "us," "our," and similar designations refer to Entrada Therapeutics, Inc. and, where appropriate, our wholly-owned subsidiary.

SUMMARY OF MATERIAL AND OTHER RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties and are subject to change based on various factors, including those highlighted in the section entitled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q ("Quarterly Report"). These risks include, but are not limited to, the following:

- We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue from product sales or become profitable or, if we achieve profitability, we may not be able to sustain it.
- We will require additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.
- We have identified conditions that raise substantial doubt about our ability to continue as a going concern. If we fail to obtain additional financing or cannot obtain financing at the levels we require, we may be forced to delay, reduce or discontinue our plans and operations or unable to complete the development and commercialization of our product candidates.
- We are early in our development efforts and as a result it will be years before we commercialize a therapeutic candidate, if ever. If we are unable to identify and advance therapeutic candidates through preclinical studies and/or clinical trials, obtain marketing approval and ultimately commercialize them, or experience significant delays in doing so, our business will be materially harmed.
- Our business is highly dependent on the clinical advancement of our programs and modalities and is especially dependent on the success of our lead therapeutic candidates, ENTR-601-44 and ENTR-601-45, as well as ENTR-601-50, ENTR-601-51, ENTR-801 and our partnered candidate VX-670. Delay or failure to advance programs or modalities, including ENTR-601-44, ENTR-601-45, ENTR-601-50, ENTR-601-51, ENTR-801 and VX-670 could adversely impact our business.
- Our Endosomal Escape Vehicle ("EEV") therapeutic candidates are based on a novel therapeutic approach, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all.
- Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies are not necessarily predictive of the results of later preclinical studies and any clinical trials of our therapeutic candidates. We have not completed the testing of any of our therapeutic candidates in clinical trials and our therapeutic candidates may not have favorable results in clinical trials, if any, or receive regulatory approval on a timely basis, if at all.
- Substantial delays in the commencement, enrollment or completion of our planned clinical trials, or failure to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities could prevent us from commercializing any therapeutic candidates we determine to develop on a timely basis, if at all.
- Our approach to the discovery and development of therapeutic candidates that are based on our EEV platform ("EEV Platform") is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our therapeutic candidates or render our EEV Platform obsolete.
- We rely, and expect to continue to rely, on third parties to conduct some or all aspects of our product manufacturing, research and preclinical and clinical testing, and these third parties may not perform satisfactorily or, dedicate adequate resources to meet our needs, or may be unable to acquire the necessary supplies to perform successfully.
- We have and may in the future enter into collaborations, licenses and other similar arrangements with third parties for the research, development and commercialization of certain of the therapeutic candidates we may develop, including our collaboration with Vertex Pharmaceuticals Incorporated ("Vertex"). If any such arrangements are not successful, we may not be able to capitalize on the market potential of those therapeutic candidates.
- We face significant competition, and if our competitors develop technologies or therapeutic candidates more rapidly than we do or their technologies are more effective, our business and our ability to develop and successfully commercialize products may be adversely affected.
- While we will attempt to diversify our risks by developing one or more programs in each modality, there are risks that are unique to each modality and risks that are applicable across modalities. These risks may impair our ability to advance one or more of our programs in clinical development, obtain regulatory approval, or ultimately

commercialize our programs, or cause us to experience significant delays in doing so, any of which may materially harm our business.

- If we or our collaborators are unable to obtain and maintain patent protection for our EEV Platform, therapeutic development programs and other proprietary technologies we develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our therapeutic programs and other proprietary technologies we may develop may be adversely affected.
- Our future success depends on our ability to retain key employees and to attract, retain and motivate qualified personnel.
- The market price of our common stock may be volatile, and investors could lose all or part of their investment.
- Volatility in capital markets may affect our ability to access new capital, which may harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.
- Unstable market and economic conditions may have adverse consequences for our business, financial condition and stock price.

The material and other risks summarized above should be read together with the text of the full risk factors and in the other information set forth in this Quarterly Report, including our condensed consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission (the "SEC"). If any such material and other risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations.

PART I —FINANCIAL INFORMATION

Item 1. Financial Statements

ENTRADA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 112,238	$ 90,394
Marketable securities	80,777	205,304
Restricted cash, current portion	—	658
Collaboration receivable	838	1,177
Prepaid expenses and other current assets	9,101	8,719
Total current assets	202,954	306,252
Property and equipment, net	5,213	7,313
Restricted cash	3,292	3,292
Right-of-use assets, operating leases	55,298	60,451
Other non-current assets	123	70
Total assets	$ 266,880	$ 377,378
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,865	$ 2,289
Accrued expenses and other current liabilities	16,279	17,682
Operating lease obligations, current portion	4,621	4,138
Deferred revenue	98	342
Total current liabilities	25,863	24,451
Operating lease obligations, net of current portion	42,692	46,794
Total liabilities	68,555	71,245
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, par value $0.0001; 150,000,000 shares authorized; 39,150,334 shares issued and outstanding as of September 30, 2026; and 38,284,221 shares issued and outstanding as of December 31, 2025	4	4
Additional paid-in capital	593,693	578,571
Accumulated other comprehensive (loss) income	(56)	652
Accumulated deficit	(395,316)	(273,094)
Total stockholders' equity	198,325	306,133
Total liabilities and stockholders' equity	$ 266,880	$ 377,378

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

ENTRADA 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,	
	2026	2025	2026	2025
Collaboration revenue	$ 905	$ 1,614	$ 2,678	$ 24,122
Operating expenses:				
Research and development	32,369	38,361	100,792	108,312
General and administrative	10,225	10,304	30,841	31,500
Total operating expenses	42,594	48,665	131,633	139,812
Loss from operations	(41,689)	(47,051)	(128,955)	(115,690)
Other income:				
Interest and other income	1,974	3,571	6,833	11,936
Total other income	1,974	3,571	6,833	11,936
Loss before provision for income taxes	(39,715)	(43,480)	(122,122)	(103,754)
Provision for income taxes	27	654	100	832
Net loss	$ (39,742)	$ (44,134)	$ (122,222)	$ (104,586)
Net loss per share, basic and diluted	$ (0.94)	$ (1.06)	$ (2.90)	$ (2.53)
Weighted-average common shares outstanding, basic and diluted	42,373,345	41,462,567	42,145,729	41,293,108
Other comprehensive (loss) gain				
Unrealized (loss) gain on marketable securities	(122)	221	(708)	664
Total other comprehensive (loss) gain	(122)	221	(708)	664
Total comprehensive loss	$ (39,864)	$ (43,913)	$ (122,930)	$ (103,922)

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

ENTRADA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2025	38,284,221	$ 4	$ 578,571	$ 652	$ (273,094)	$ 306,133
Issuance of common stock upon exercise of stock options	10,104	—	100	—	—	100
Vesting of restricted stock units	526,291	—	—	—	—	—
Stock-based compensation	—	—	4,744	—	—	4,744
Other comprehensive loss	—	—	—	(406)	—	(406)
Net loss	—	—	—	—	(39,717)	(39,717)
Balances at March 31, 2026	38,820,616	$ 4	$ 583,415	$ 246	$ (312,811)	$ 270,854
Issuance of common stock upon exercise of stock options	16,923	—	30	—	—	30
Vesting of restricted stock units	41,979	—	—	—	—	—
Purchase of common stock under the employee stock purchase plan	57,151	—	320	—	—	320
Stock-based compensation	—	—	5,150	—	—	5,150
Other comprehensive loss	—	—	—	(180)	—	(180)
Net loss	—	—	—	—	(42,763)	(42,763)
Balances at June 30, 2026	38,936,669	$ 4	$ 588,915	$ 66	$ (355,574)	$ 233,411
Vesting of restricted stock units	213,665	—	—	—	—	—
Stock-based compensation	—	—	4,778	—	—	4,778
Other comprehensive loss	—	—	—	(122)	—	(122)
Net loss	—	—	—	—	(39,742)	(39,742)
Balances at September 30, 2026	39,150,334	$ 4	$ 593,693	$ (56)	$ (395,316)	$ 198,325

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2024	37,574,538	$ 4	$ 558,061	$ (43)	$ (129,344)	$ 428,678
Issuance of common stock upon exercise of stock options	40,984	—	350	—	—	350
Vesting of early exercised options	1,676	—	14	—	—	14
Vesting of restricted stock units	325,085	—	—	—	—	—
Stock-based compensation	—	—	5,087	—	—	5,087
Other comprehensive income	—	—	—	480	—	480
Net loss	—	—	—	—	(17,349)	(17,349)
Balances at March 31, 2025	37,942,283	$ 4	$ 563,512	$ 437	$ (146,693)	$ 417,260
Issuance of common stock upon exercise of stock options	12,106	—	20	—	—	20
Vesting of restricted stock units	29,163	—	—	—	—	—
Purchase of common stock under the employee stock purchase plan	50,418	—	317	—	—	317
Stock-based compensation	—	—	5,048	—	—	5,048
Other comprehensive income	—	—	—	(37)	—	(37)
Net loss	—	—	—	—	(43,103)	(43,103)
Balances at June 30, 2025	38,033,970	$ 4	$ 568,897	$ 400	$ (189,796)	$ 379,505
Issuance of common stock upon exercise of stock options	3,109	—	8	—	—	8
Vesting of restricted stock units	182,153	—	—	—	—	—
Stock-based compensation	—	—	5,116	—	—	5,116
Other comprehensive income	—	—	—	221	—	221
Net loss	—	—	—	—	(44,134)	(44,134)
Balances at September 30, 2025	38,219,232	$ 4	$ 574,021	$ 621	$ (233,930)	$ 340,716

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

ENTRADA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(unaudited)

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (122,222)	$ (104,586)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	2,316	3,210
Stock-based compensation expense	14,672	15,251
Amortization/(accretion) of marketable securities	(1,255)	(3,038)
Changes in operating assets and liabilities:		
Collaboration receivable	339	2,484
Prepaid expenses and other current assets	(382)	6,138
Right-of-use assets, operating leases	5,153	8,998
Other non-current assets	(53)	121
Accounts payable	2,576	(922)
Accrued expenses and other current liabilities	(1,403)	2,592
Income tax payable	—	(47)
Operating lease liabilities	(3,619)	(6,807)
Deferred revenue	(244)	(19,703)
Net cash used in operating activities	(104,122)	(96,309)
Cash flows from investing activities:		
Purchases of property and equipment	(216)	(1,248)
Purchases of marketable securities	(23,666)	(123,140)
Maturities of marketable securities	148,740	212,077
Net cash provided by investing activities	124,858	87,689
Cash flows from financing activities:		
Proceeds from exercise of stock options	130	378
Proceeds from issuance of common stock under the employee stock purchase plan	320	317
Net cash provided by financing activities	450	695
Net increase (decrease) in cash, cash equivalents and restricted cash	21,186	(7,925)
Cash, cash equivalents, and restricted cash at beginning of period	94,344	105,161
Cash, cash equivalents, and restricted cash at end of period	$ 115,530	$ 97,236
Supplemental cash flow disclosures:		
Vesting of options early exercised subject to repurchase	$ —	$ 14

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

ENTRADA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. Nature of the Business

Organization

Entrada Therapeutics, Inc. ("Entrada" or the "Company") is a clinical-stage biopharmaceutical company aiming to transform the lives of patients by establishing a new class of medicines that engage intracellular targets that have long been considered inaccessible. Through proprietary, versatile and modular approaches, Entrada is advancing a robust development portfolio of genetic medicines for the potential treatment of neuromuscular and inherited retinal diseases, among others. The Company was incorporated in Delaware on September 22, 2016, and its principal offices are located in Boston, Massachusetts.

Liquidity and Capital Resources

Since its inception, the Company has devoted substantially all of its resources to its research and development efforts relating to its proprietary, highly versatile and modular EEV platform ("EEV Platform"), advancing development of its portfolio of programs and general and administrative support for these operations, including raising capital. The Company is subject to risks and uncertainties common to earlier-stage companies in the biotechnology industry, including, but not limited to, technical risks associated with the successful research, development and manufacturing of therapeutic candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and the ability to secure additional capital to fund operations. Therapeutic candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel and infrastructure. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

In accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. Since its inception, the Company has incurred significant net losses and expects to continue to generate operating losses and negative operating cash flows for the foreseeable future. As of September 30, 2026, the Company had an accumulated deficit of $395.3 million. To date, the Company has funded its operations primarily through the sale of equity securities and collaboration payments.

The Company expects that its cash, cash equivalents and marketable securities of $193.0 million as of September 30, 2026 will be sufficient to fund its operations and capital expenditure requirements into the fourth quarter of 2027. This estimate is based on the Company's current operating plan and excludes the potential effects of any future financing events or milestone payments that may be received under the Vertex Agreement. These conditions raise substantial doubt about the Company's ability to continue as a going concern within 12 months from the date these condensed consolidated financial statements are issued.

The Company will need additional financing to pursue its business strategy and may pursue additional cash resources through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing or other arrangements. There is no assurance that the Company will be successful in obtaining sufficient funding on acceptable terms, if at all.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

2. Summary of Significant Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements as of and for the three and nine months ended September 30, 2026 are consistent with those discussed in Note 2 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended

December 31, 2025, which was filed with the Securities and Exchange Commission (the "SEC") on February 26, 2026 (the "Annual Report"), except as described below.

Basis of Presentation

The accompanying condensed consolidated financial statements are unaudited and have been prepared in conformity with generally accepted accounting principles in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the ASC and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). The condensed consolidated financial statements have been prepared on the same basis as the audited annual financial statements. Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted, as is permitted by GAAP. These condensed consolidated financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position as of September 30, 2026 and December 31, 2025, and results of operations for the interim periods ended September 30, 2026 and 2025.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These condensed consolidated financial statements should be read in conjunction with the audited financial statements as of and for the years ended December 31, 2025 and 2024, and the notes thereto, included in the Annual Report.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that are adopted by the Company as of the specified effective date. Except as noted below, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which is intended to provide enhancements to annual income tax disclosures. In particular, the standard will require more detailed information in the income tax rate reconciliation, as well as the disclosure of income taxes paid disaggregated by jurisdiction, among other enhancements. The standard is effective for annual reporting periods beginning after December 15, 2024 for public business entities ("PBEs") and for annual reporting periods beginning after December 15, 2025 for all other entities. Early adoption is permitted. The Company has availed itself of the extended transition period afforded to EGCs and will adopt this ASU in connection with filing its 2026 annual financial statements. ASU 2023-09 will result in the required additional disclosures being included in the Company’s annual consolidated financial statements.

In November 2024, the FASB issued *ASU 2024-03, Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures*. The ASU requires PBEs to provide disaggregated disclosures of certain categories of expenses on an annual and interim basis including purchases of inventory, employee compensation, depreciation, and intangible asset amortization for each income statement line item that contains those expenses. This ASU is effective for annual reporting periods beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of the standard on its disclosures.

3. Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with an original maturity of 90 days or less at the date of purchase to be cash equivalents. At September 30, 2026 and December 31, 2025, cash and cash equivalents include standard checking accounts and money market account funds that invest primarily in U.S. government-backed securities and treasuries.

As of September 30, 2026 and December 31, 2025, restricted cash represents collateral provided for a letter of credit issued as a security deposit in connection with the Company's lease of its corporate facilities located at One Design Center Place, Boston, Massachusetts. A reconciliation of the cash, cash equivalents, and restricted cash reported within the balance sheet that sum to the total of the same amounts shown in the statement of cash flows is as follows (in thousands):

	September 30, 2026	December 31, 2025
Cash and cash equivalents	$ 112,238	$ 90,394
Restricted cash, current portion	—	658
Restricted cash, net of current portion	3,292	3,292
Total cash, cash equivalents and restricted cash	$ 115,530	$ 94,344

4. Marketable Securities

The following are summaries of the Company's marketable securities at September 30, 2026 and December 31, 2025 (in thousands).

	As of September 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government agency securities and treasuries	$ 67,869	$ 4	$ (16)	$ 67,857
Corporate debt securities	4,974	—	(4)	4,970
Total securities with a maturity of one year or less	$ 72,843	$ 4	$ (20)	$ 72,827
U.S. government agency securities and treasuries	7,990	—	(40)	7,950
Total securities with a maturity of more than one year	$ 7,990	$ —	$ (40)	$ 7,950
Total marketable securities	$ 80,833	$ 4	$ (60)	$ 80,777

	As of December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government agency securities and treasuries	$ 179,958	$ 494	$ —	$ 180,452
Corporate debt securities	11,775	5	—	11,780
Total securities with a maturity of one year or less	$ 191,733	$ 499	$ —	$ 192,232
U.S. government agency securities and treasuries	7,985	133	—	8,118
Corporate debt securities	4,934	20	—	4,954
Total securities with a maturity of more than one year	$ 12,919	$ 153	$ —	$ 13,072
Total marketable securities	$ 204,652	$ 652	$ —	$ 205,304

As of September 30, 2026, the Company had 8 marketable securities with a total fair market value of $44.8 million in an unrealized loss position. All of the Company's investments are classified as available-for-sale and are carried at fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income (loss). The Company considers all available-for-sale securities, including those with maturity dates beyond 12 months, as available to support current operational liquidity needs and therefore classifies all securities as available for sale.

The Company believes that any unrealized losses associated with the decline in value of its securities are temporary and believes that it is more likely than not that it will be able to hold its debt securities to maturity and that there

was no material change in the credit risk of the above instruments since January 1, 2026. Therefore, the Company anticipates a full recovery of the amortized cost basis of its debt securities at maturity and no allowance for credit losses was recognized.

As of September 30, 2026 and December 31, 2025, $0.8 million and $1.4 million, respectively, of accrued interest receivable was included in prepaid expenses and other current assets.

5. Fair Value Measurements

The following tables present the Company's fair value hierarchy for its assets that are measured at fair value on a recurring basis and indicate the level within the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value (in thousands):

	Fair Value Measurements at September 30, 2026			
	Level 1	Level 2	Level 3	Total
Cash equivalents: [1]				
Money market funds	$ 111,988	$ —	$ —	$ 111,988
Marketable securities:				
U.S. government agency securities and treasuries	—	75,807	—	75,807
Corporate bonds	—	4,970	—	4,970
Total	$ 111,988	$ 80,777	$ —	$ 192,765

	Fair Value Measurements at December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents: [1]				
Money market funds	$ 89,894	$ —	$ —	$ 89,894
Marketable securities:				
U.S. government agency securities and treasuries	—	188,570	—	188,570
Corporate bonds	—	16,734	—	16,734
Total	$ 89,894	$ 205,304	$ —	$ 295,198

(1) The cash equivalent amounts above do not include $0.3 million and $0.5 million of cash related to checking accounts included in cash and cash equivalents as of September 30, 2026 and December 31, 2025, respectively. These amounts are excluded as no valuation is needed for cash in checking accounts.

Money market funds are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets. The Company measures its debt securities at fair value on a recurring basis using inputs that are observable or can be corroborated by observable market data and classifies those instruments within Level 2 of the fair value hierarchy.

6. Property and Equipment, Net

Property and equipment, net consisted of the following at September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026	December 31, 2025
Laboratory equipment	$ 13,684	$ 14,428
Furniture and fixtures	2,223	2,223
Computer equipment	465	409
Leasehold improvements	187	187
Property and equipment, gross	16,559	17,247
Less: accumulated depreciation	(11,346)	(9,934)
Property and equipment, net	$ 5,213	$ 7,313

Depreciation expense for the three months ended September 30, 2026 and 2025 was $0.7 million and $1.2 million, respectively. Depreciation expense for the nine months ended September 30, 2026 and 2025 was $2.3 million and $3.2 million, respectively.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following at September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026	December 31, 2025
Employee compensation and benefits	$ 6,124	$ 8,045
External research and development expenses	8,527	8,048
General and administrative professional service expenses	659	415
Other	969	1,174
Total accrued expenses and other current liabilities	$ 16,279	$ 17,682

8. Common Stock and Preferred Stock

Common Stock

As of September 30, 2026 and December 31, 2025, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 150,000,000 shares of common stock, par value $0.0001 per share.

As of both September 30, 2026 and December 31, 2025, there were pre-funded warrants outstanding to purchase 3,367,000 shares of common stock, with an exercise price of $0.0001 per share (the "Pre-Funded Warrants"). The Pre-Funded Warrants do not expire and are exercisable at any time, subject to certain ownership limitations. The Company classified the Pre-Funded Warrants as a component of permanent stockholders' equity within additional paid-in capital, and they were recorded at the issuance date at fair value.

In November 2025, the Company entered into a sales agreement (the "Sales Agreement"), with TD Securities (USA) LLC (f/k/a Cowen and Company, LLC), acting as the Company's agent and/or principal (the "Sales Agent"), with respect to an "at the market offering" program under which the Company may, from time to time, at its sole discretion, issue and sell shares of its common stock having an aggregate offering price of up to $150.0 million through the Sales Agent. During the three months ended September 30, 2026, there have been no sales of common stock pursuant to the Sales Agreement.

Shares Reserved for Future Issuance under Equity Compensation Plans

The Company has reserved the following shares of common stock for future issuance under equity compensation plans as of:

	September 30, 2026	December 31, 2025
Exercise of outstanding stock options	6,624,824	5,960,989
Vesting of outstanding restricted stock units	2,643,460	2,284,277
Vesting of outstanding performance stock units	441,250	438,500
Future awards under the 2021 Stock Option and Incentive Plan	1,177,847	1,383,679
Future awards under the 2021 Employee Stock Purchase Plan	1,755,292	1,429,601
Future awards under the 2025 Inducement Plan	466,850	79,380
Total shares of authorized common stock reserved for future issuance	13,109,523	11,576,426

Preferred Stock

As of September 30, 2026 and December 31, 2025, the Company was authorized to issue 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share, in one or more series and to fix the rights, preferences, privileges and restrictions thereof. As of September 30, 2026 and December 31, 2025, there were no shares of undesignated preferred stock issued or outstanding.

9. Stock-Based Compensation

Stock-based compensation expense recorded in the condensed consolidated statements of operations and comprehensive loss is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development expenses	$ 2,328	$ 2,276	$ 6,868	$ 6,783
General and administrative expenses	2,450	2,840	7,804	8,468
Total	$ 4,778	$ 5,116	$ 14,672	$ 15,251

Stock Option Valuation

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option-pricing model to determine the fair value of stock options granted during the nine months ended September 30, 2026 and 2025:

	September 30, 2026	September 30, 2025
Risk-free interest rate	3.70 %	4.03 %
Expected volatility	85 %	79 %
Expected dividend yield	—	—
Expected term (in years)	6.00	6.00

Stock Options

The following table summarizes the Company's stock option activity during the nine months ended September 30, 2026:

	Number of Shares		Weighted-Average Exercise Price
Outstanding as of December 31, 2025	5,960,989	$	11.73
Granted	903,025		11.07
Exercised	(27,027)		4.83
Forfeited	(212,163)		13.50
Outstanding as of September 30, 2026	6,624,824	$	11.61
Exercisable as of September 30, 2026	4,986,409	$	11.62

The weighted-average grant-date fair value of stock options granted during the nine months ended September 30, 2026 and 2025 was $8.12 per share and $7.74 per share, respectively. As of September 30, 2026, there was $12.0 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.6 years.

Restricted Stock Units

During the nine months ended September 30, 2026, restricted stock units ("RSUs") were granted to employees with vesting conditions based on continued service over time. Accordingly, stock-based compensation expense for such awards is recognized using a straight-line attribution model over the vesting term of each RSU. The fair value of each RSU is based on the closing price of the Company's common stock on the date of grant.

A summary of restricted stock activity during the nine months ended September 30, 2026 is as follows:

	Shares		Weighted-Average Grant-Date Fair Value
Unvested as of December 31, 2025	2,284,277	$	12.76
Granted	1,291,895	$	11.08
Vested	(781,935)	$	13.12
Forfeited	(150,777)	$	12.52
Unvested as of September 30, 2026	2,643,460	$	11.84

As of September 30, 2026, there was $25.8 million of unrecognized stock-based compensation expense related to restricted stock that is expected to vest. These costs are expected to be recognized over a weighted-average remaining vesting period of 2.6 years.

Performance Stock Units

As of September 30, 2026 and December 31, 2025, there were 441,250 and 438,500 performance stock units ("PSUs") outstanding, respectively. During the nine months ended September 30, 2026, 243,750 PSUs were granted and 241,000 PSUs were forfeited. The outstanding PSUs will vest upon achievement of certain clinical milestones and continued employment thereafter.

As of September 30, 2026, no PSUs have vested and no stock-based compensation expense has been recognized as achievement of the performance conditions was not deemed probable. As of September 30, 2026, there was $4.6 million of unrecognized stock-based compensation expense related to unvested PSUs.

10. Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities. These differences are measured using the enacted statutory tax rates that are expected to be in effect for the years in which differences are expected to reverse. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. The Company continues to maintain a full valuation allowance against all of its deferred tax assets based on its evaluation of all available evidence.

There were no significant income tax provisions or benefits recorded for the three and nine months ended September 30, 2026. The Company recorded income tax expense of $0.7 million for the three months ended September 30, 2025 and $0.8 million for the nine months ended September 30, 2025. For the three and nine months ended September 30, 2025, the income tax provision recorded was primarily driven by adjustments made upon the finalization of tax returns.

11. Commitments and Contingencies

The Company's commitments, including significant license agreements, are disclosed in Note 10 *Commitments and Contingencies* in the audited financial statements for the year ended December 31, 2025, and notes thereto, included in the Annual Report. Since the date of those financial statements, there have been no material changes to its commitments.

12. Collaboration and License Agreements

Vertex Agreement

The Company and Vertex closed their Strategic Collaboration and License Agreement in February 2023, as amended in October 2023 (the "Vertex Agreement"), pursuant to which the Company granted Vertex an exclusive worldwide license to research, develop, manufacture and commercialize VX-670, the Company's intracellular EEV-based therapeutic candidate for the treatment of myotonic dystrophy type 1 ("DM1"), as well as any additional EEV-based therapeutic candidates that may be identified by the Company for the potential treatment of DM1 in the course of the parties' global research collaboration.

The Vertex Agreement provides for a four-year global research collaboration under which Entrada will continue to perform preclinical development of the Company's partnered candidate VX-670, as well as work on additional EEV-based therapeutic candidates for the potential treatment of DM1 (the "Research Plan"). Vertex is obligated to reimburse the Company's research expenses incurred in performing activities under the Research Plan.

The Company determined that the Vertex Agreement contains two performance obligations: (1) the combination of the exclusive license and the performance of the research activities for VX-670 ("Performance Obligation One") and (2) research activities performed on additional EEV-based therapeutic candidates for the potential treatment of DM1 ("Performance Obligation Two"). As of September 30, 2026, Performance Obligation One is complete and the Company continues to perform research activities for Performance Obligation Two.

During the three months ended September 30, 2026, the Company recognized $0.9 million in revenue under the Vertex Agreement, including $0.8 million of cost reimbursements and $0.1 million from amounts that were recorded in deferred revenue as of December 31, 2025. During the nine months ended September 30, 2026, the Company recognized $2.7 million in revenue under the Vertex Agreement, including $2.4 million of cost reimbursements and $0.3 million from amounts that were recorded in deferred revenue as of December 31, 2025.

During the three months ended September 30, 2025, the Company recognized $1.6 million of revenue under the Vertex Agreement, including $1.2 million of cost reimbursements and $0.4 million from amounts recorded in deferred revenue as of December 31, 2024. During the nine months ended September 30, 2025, the Company recognized $24.1 million of revenue under the Vertex Agreement, including $4.0 million of cost reimbursements and $20.1 million from amounts recorded in deferred revenue as of December 31, 2024.

The aggregate amount of the transaction price allocated to the Company's unsatisfied performance obligation recorded in deferred revenue at September 30, 2026 is $0.1 million. The Company will recognize the deferred revenue related to the research and development services based on a cost input method, over the remaining term of the Research Plan.

13. Net Loss per Share

The computation of basic net loss per share is based on the weighted-average number of the Company's common shares outstanding. The weighted-average common shares outstanding used in the basic and diluted net loss per share calculation includes the outstanding Pre-Funded Warrants as they are exercisable for nominal cash consideration.

The computation of diluted net loss per share is based on the weighted-average number of the Company's common shares outstanding and potential dilutive common shares outstanding during the period as determined by using the treasury stock method.

The following table illustrates the determination of basic and diluted net loss per share for each period presented (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (39,742)	$ (44,134)	$ (122,222)	$ (104,586)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	42,373,345	41,462,567	42,145,729	41,293,108
Net loss per share, basic and diluted	$ (0.94)	$ (1.06)	$ (2.90)	$ (2.53)

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 attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Unvested restricted stock units	2,643,460	2,357,675	2,643,460	2,357,675
Unvested performance stock units	441,250	438,500	441,250	438,500
Stock options to purchase common stock	6,624,824	5,947,177	6,624,824	5,947,177
	9,709,534	8,743,352	9,709,534	8,743,352

14. Segment Information

The Company manages its operations as a single segment. The Company's Chief Operating Decision Maker ("CODM"), its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of assessing performance and making operating decisions. The segment measure of profit or loss is consolidated net loss.

The following table presents selected financial information with respect to the Company's single operating segment for each period presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Collaboration revenue	$ 905	$ 1,614	$ 2,678	$ 24,122
Less:				
Research and development expenses				
Direct research and development expenses				
ENTR-601-44	6,245	6,568	18,213	15,748
ENTR-601-45	4,467	3,543	11,098	10,978
ENTR-601-50	254	3,164	3,350	5,896
ENTR-601-51	794	2,807	4,391	6,488
DMD franchise-wide[(1)]	1,475	883	6,700	2,595
Collaboration services	293	534	828	1,937
Ocular programs	863	791	1,973	1,603
Other preclinical and discovery	511	490	1,517	2,159
Unallocated research and development expenses				
Personnel related (including stock-based compensation)	11,948	11,549	35,785	37,536
Facility related and other	5,519	8,032	16,937	23,372
Total research and development expenses	32,369	38,361	100,792	108,312
General and administrative expenses	10,225	10,304	30,841	31,500
Interest and other income	1,974	3,571	6,833	11,936
Provision for (benefit from) income taxes	27	654	100	832
Net loss	$ (39,742)	$ (44,134)	$ (122,222)	$ (104,586)

(1) Represents manufacturing and clinical costs that support across the Company's product candidates targeting DMD.

Assets regularly provided to the CODM are consistent with those reported on the condensed consolidated balance sheets with particular emphasis on the Company's available liquidity, including its cash, cash equivalents and marketable securities balances. All of the Company's tangible assets are held in the United States.

15. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the condensed consolidated financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. The Company has concluded that no subsequent events have occurred that require disclosure.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q ("Quarterly Report") and the audited financial information and the notes thereto included in the Company's Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission (the "SEC") on February 26, 2026 ("Annual Report"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Cautionary Note Regarding Forward-Looking Statements" and *"Risk Factors" section of this Quarterly Report, 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. You should carefully read the "Cautionary Note Regarding Forward-Looking Statements"* and *"Risk Factors" sections of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements contained in the following discussion and analysis.*

Overview

We are a clinical-stage biopharmaceutical company aiming to transform the lives of patients by establishing a new class of medicines that engage intracellular targets that have long been considered inaccessible. Through proprietary, versatile and modular approaches, we are advancing a robust development portfolio of genetic medicines for the potential treatment of neuromuscular and inherited retinal diseases, among others. In 2026, we have been actively progressing our ELEVATE-44 and ELEVATE-45 clinical trials. In addition, our VX-670 partnership with Vertex Pharmaceuticals Incorporated ("Vertex") continues to progress, with Vertex on track to share interim results in the second half of 2026. In addition to the ELEVATE-45-201 Cohort 1 results included in this Quarterly Report, we anticipate additional ELEVATE-44-201 Cohort 1 open-label data by the end of 2026. We anticipate topline data from Cohort 2 of our ELEVATE-44-201 multiple ascending dose ("MAD") trial in the first quarter of 2027 and to report our Cohort 2 ELEVATE-45-201 MAD data in the first half of 2027. We expect that our cash, cash equivalents and marketable securities of $193.0 million as of September 30, 2026 will be sufficient to fund our operations and capital expenditure requirements into the fourth quarter of 2027.

Clinical-Stage Development Pipeline:

Entrada continues to advance multiple clinical programs in people living with Duchenne muscular dystrophy ("DMD") in the United Kingdom ("U.K."), European Union ("EU") and United States ("U.S."). In 2026, we have four clinical-stage programs in our DMD franchise (ENTR-601-44, ENTR-601-45, ENTR-601-50 and ENTR-601-51, which has completed CTA-enabling studies but has not yet filed a regulatory application). When combined, we estimate that there are over 11,500 patients in the U.S. and Europe that carry mutations amenable to Entrada's current exon skipping programs. Complementing the ongoing clinical progress of the DMD franchise is the myotonic dystrophy type 1 ("DM1") partnership with Vertex ("VX-670"). Each of these programs utilize the same endosomal escape vehicle, and as such, we anticipate initial data readouts from any one of the candidate clinical trials to provide critical insights for the rest.

ELEVATE-44-201: All eight of the previously treated and placebo participants from Cohort 1 have received their final dose in the 6-dose open-label period of the study and have rolled into the long-term extension (LTE) study. Data from the open-label period remains on track to be received by the end of 2026. A continuation of safety and functional benefit in the open-label period of the study would strengthen the competitive profile of the program. Enrollment is complete for Cohort 2 of the global Phase 1/2 MAD portion of the study at the increased dose of 12 mg/kg, and we expect to report topline results including safety, exon skipping, dystrophin and functional readouts in the first quarter of 2027. Data from Cohort 3 will follow. In the third quarter of 2026, an independent Data Monitoring Committee ("DMC"), per study protocol, reviewed all available safety and pharmacokinetics data from Cohort 2 of the double-blind, placebo-controlled, MAD portion of ELEVATE-44-201. The DMC recommended initiation of the Cohort 3 dose at 18 mg/kg, a dose escalation from 12 mg/kg in Cohort 2. We anticipate seeing an increase in dystrophin and improvements in functional responses as we increase dosing amounts in the second and third cohorts. We also intend to open an expansion cohort to increase the number of participants treated in the ELEVATE-44-201 study, as this study has been designed to support an accelerated approval in the U.S.

ELEVATE-44-102: We believe this clinical trial, in the underserved adult patient population, would be best to initiate at the highest advisable starting dose in patients with advanced disease. Following a review of safety,

pharmacokinetic and pharmacodynamic data from our lead programs in the U.K. and EU, we will continue to engage with the FDA and will provide an update on the clinical study design and timing when appropriate.

ELEVATE-45-201: We reported data from Cohort 1 (5 mg/kg) in October 2026. Study participants in Cohort 1 received three doses of 5 mg/kg of ENTR-601-45 or placebo. Topline results met the primary objective of a favorable safety and tolerability profile. Importantly, no hypomagnesemia or renal safety concerns were noted. The secondary objectives also met our expectations. A 0.10% mean increase in dystrophin and a 0.15% mean increase in exon skipping compared with baseline levels was observed in treated participants. All participants from Cohort 1 have transitioned into the open-label, Phase 2 portion of the study. Cohort 2 is dosing at 10 mg/kg and is ongoing. Data from Cohort 2 is expected in the first half of 2027, and data from Cohort 3 (up to 15 mg/kg) is expected to follow. The ELEVATE-45-201 clinical trial design and dosing regimen is similar to ELEVATE-44-201, incorporating a MAD Phase 1 portion, a 6 dose open-label Phase 2 portion and an expansion cohort. We expect ENTR-601-45, at higher doses, has the potential to be both best in class and to be the first PMO-conjugate to generate clinically meaningful data in a population where low single digit competitive dystrophin production has been observed to date. In October 2026, the U.S. FDA Office of Orphan Products Development (OOPD) granted orphan drug designation for ENTR-601-45 for the treatment of DMD.

ELEVATE-LTE: A LTE platform study protocol (ENTR-DMD-202) was accepted by U.K. and European authorities, and patients who have completed the open-label portion of their Phase 1/2 trials are eligible to roll over into the LTE. This is a Phase 2, open-label long-term extension study in participants with Duchenne muscular dystrophy amenable to exon skipping to assess the long-term safety, tolerability, pharmacokinetics, and efficacy of endosomal escape vehicle phosphorodiamidate morpholino oligomer platform products which will enable continued access to drug for study participants while collecting longer-term safety and efficacy data, including functional measures.

ELEVATE-50-201 and ENTR-601-51: We expect to submit additional regulatory applications following a review of data from the ongoing trials of our lead programs. We are evaluating a variety of options to optimize clinical study execution, and we expect to provide more specific timeline guidance as the new strategy is finalized.

VX-670: Vertex has completed enrollment and dosing in the MAD portion of the GALILEO global Phase 1/2 clinical trial of VX-670 in people with DM1. The study is assessing both safety and preliminary efficacy, as measured by the change from baseline in the splicing index on muscle biopsy as well as other endpoints, including those that evaluate muscle function and strength, such as video hand opening time (vHOT) and quantitative muscle testing (QMT) score. Vertex is on track to share interim results from the GALILEO study in the second half of 2026.

Expanding Preclinical Pipeline:

The Company has advanced two ocular programs into lead optimization for the potential treatment of inherited retinal diseases. Both programs are novel oligonucleotide-based therapeutics with the potential to address areas of high unmet need. In December 2025, Entrada announced its first ocular clinical candidate, ENTR-801, for the potential treatment of Usher syndrome type 2A ("USH2A"). The Company plans to nominate a second clinical candidate in ocular diseases by year-end 2026 and continues to explore novel targets to address both rare and more common retinal conditions. From a strategic point of view, progress in a new therapeutic area enables portfolio diversification in the form of tissue type, route of administration and regulatory pathway. At the same time, however, as in our neuromuscular franchise, initial targets are selected based on well-understood biology, significant unmet need, translational clarity and the potential to differentiate based on our proprietary technologies and capabilities.

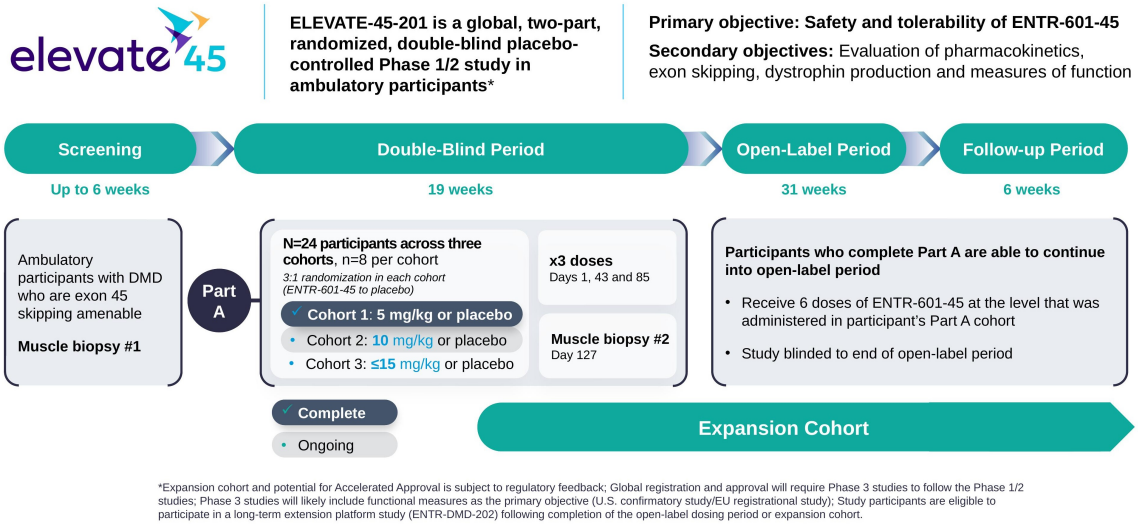
ENTR-801: The Company's first ocular candidate is an optimized, proprietary oligonucleotide-based therapy for the potential treatment of a subgroup of patients with USH2A, who are amenable to exon 13 skipping. The clinical candidate was designed to restore functional usherin protein production with the goal of preserving photoreceptors (the light-sensing cells in the eye) to stabilize the overall retinal architecture and preserve function. ENTR-801 was selected from a library of 200 sequences based on its robust exon skipping and usherin protein production, as well as initial safety data in multiple animal models.

We continue to believe that the robust supporting data and ongoing progress of our growing portfolio of clinical and preclinical candidates has the potential to make a significant difference in the lives of patients.

ENTR-601-45-201 (ELEVATE-45-201) Phase 1/2 Cohort 1 Results

Clinical Trial Overview

ELEVATE-45-201 is a global, two-part, randomized, double-blind, placebo-controlled Phase 1/2 study evaluating the safety, tolerability and effectiveness of ENTR-601-45 in ambulatory participants ages four to twenty with DMD who are exon 45 skipping amenable. The multiple ascending dose Part A portion of the study is evaluating the safety, pharmacokinetics, pharmacodynamics and functional parameters following intravenous administration of ENTR-601-45 to study participants in three cohorts at sites in the U.K. and EU. The MAD portion of the study enrolled eight participants with DMD in Cohort 1. They were randomized 3:1 to receive ENTR-601-45 at a dose of 5 mg/kg or placebo, administered intravenously. During this double-blind period, doses were administered on days one, 43 and 85, and muscle biopsies were performed at the time of screening and at six weeks after the last dose. Following the initial three doses administered in Part A, all participants continued into the Phase 2, open-label portion in which the safety and efficacy of ENTR-601-45 are evaluated over a longer period of time.



*Expansion cohort and potential for Accelerated Approval is subject to regulatory feedback; Global registration and approval will require Phase 3 studies to follow the Phase 1/2 studies; Phase 3 studies will likely include functional measures as the primary objective (U.S. confirmatory study/EU registrational study); Study participants are eligible to participate in a long-term extension platform study (ENTR-DMD-202) following completion of the open-label dosing period or expansion cohort.

Summary of Demographics and Baseline Patient Characteristics

The average age of treated participants in Cohort 1 was 6.3 years old with a mean age of diagnosis of 1.9 years. Per protocol, all participants were ambulatory and all were on a stable dose of steroids.

Baseline Characteristics	Placebo n=2	ENTR-601-45 5 mg/kg n=6
Age, mean, years	9.0	6.3
Body mass index, mean, kg/m^2	19.75	16.62
Age at diagnosis, mean, years	4.0	1.9
Corticosteroid use, n (%)	2 (100%)	6 (100%)
Ambulatory, n (%)	2 (100%)	6 (100%)
Baseline dystrophin, mean, %	0.34%	0.49%

Dystrophin measured by western blot and normalized to MHC; Dystrophin values are actual observed values, including values <LLOQ; Two participants in the ENTR-601-45 group had baseline dystrophin levels <LLOQ and >LOD; LLOQ for dystrophin was 0.25%; LOD for dystrophin was 0.1%; Biopsy performed at baseline; **LLOQ**: Lower limit of quantification; **LOD**: Limit of detection.

Safety and Tolerability Data

Cohort 1 achieved its primary objective, demonstrating a generally favorable safety and tolerability profile. Most treatment emergent adverse events ("TEAEs") were mild to moderate. One participant experienced two serious TEAEs (vomiting and pyrexia), both of which resolved. No discontinuations were reported. All study participants in Cohort 1 have now progressed to the open-label, Phase 2 portion of the study, where they will all receive six doses of 5 mg/kg of ENTR-601-45. The most common TEAE seen was headache.

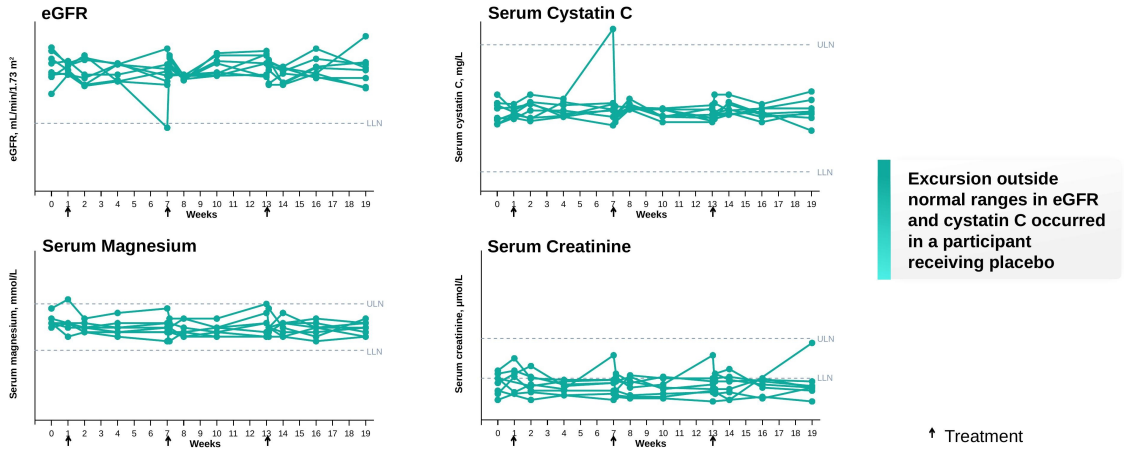
Participants with ≥1 TEAE, n (%)	Placebo n=2	ENTR-601-45 5 mg/kg n=6
Any TEAE	2 (100%)	6 (100%)
TEAEs related to study drug	2 (100%)	4 (67%)
Serious TEAEs	0	1 (17%)
TEAEs leading to study discontinuation	0	0
TEAEs leading to death	0	0

Most TEAEs were mild to moderate

- Headache was the most common TEAE (5 events in 2 participants)
- One participant experienced 2 serious TEAEs (vomiting and pyrexia)
  - Both TEAEs resolved
- There were no study discontinuations due to any causes, and all participants enrolled in the open-label extension
- **No hypomagnesemia** or renal safety concerns were noted

A favorable safety profile supports continued dose escalation

Importantly, clinically relevant markers of kidney function including eGFR, Cystatin-C and magnesium were generally within normal ranges and treated subjects were comparable to placebo. Participant level data is presented below.



Arrowheads indicate dosing at nominal study visits; Serum creatinine reference range depends on age of the participants enrolled in Cohort 1; Serum creatinine is below the reference range in individuals with DMD due to reduced muscle mass.

We believe these results to be encouraging, given that the kidney has historically been the organ of toxicity concern for PMO-based oligonucleotides and peptide conjugates in particular, and because similarly favorable safety was observed for ENTR-601-44 at 6 mg/kg in the Phase 1 healthy normal volunteer trial disclosed in 2024 and in the first cohort of the Phase 1/2 ELEVATE-44-201 trial disclosed in the first quarter of 2026.

Exon Skipping, Dystrophin and Functional Benefit

Plasma ENTR-601-45 exposures at the initial dose of 5 mg/kg were relatively low and consistent with those predicted by juvenile non-human primate ("NHP") data. Despite the low exposures, a mean increase of 0.10% (n = 6,

nominal p = 0.03) from baseline in dystrophin production was observed in study participants who received ENTR-601-45 versus a 0.02% mean decrease from baseline in study participants who received placebo. We also observed a mean increase of 0.15% (n = 5, no p-value calculated) from baseline in exon skipping in study participants who received ENTR-601-45 versus a 0.04% mean decrease from baseline in study participants who received placebo.

Based on the age of Cohort 1 participants and baseline levels of function, no functional benefit was expected or observed after three doses of ENTR-601-45. Based on Cohort 1 and juvenile NHP pharmacokinetic data observed to date, we believe that higher doses in future cohorts may result in greater increases in dystrophin production.

Clinical Trial Progress

All study participants in Cohort 1 have now progressed to the open-label, Phase 2 portion of the study, where they are receiving six additional doses of 5 mg/kg of ENTR-601-45. Additional study participants are now being dosed in Cohort 2, in which they will receive placebo or three doses of 10 mg/kg of ENTR-601-45. We expect topline safety and efficacy results from Cohort 2 in the first half of 2027.

Components of Our Results of Operations

Revenue

Substantially all of our revenue to date has been derived from the Vertex Agreement. We do not expect to generate any revenue from the sale of products unless and until such time that our product candidates have advanced through clinical development and regulatory approval, if ever. If our development efforts for our therapeutic candidates are successful and result in regulatory approval or we successfully enter into collaboration or license arrangements with third parties, we may generate revenue in the future from product sales, payments from collaboration or license arrangements including those that we may enter into with third parties, or any combination thereof.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our programs. These expenses include:

- personnel-related expenses, including salaries, related benefits, and stock-based compensation expense for individuals engaged in research and development functions;
- expenses incurred in connection with our research programs and development of our therapeutic candidates, including those incurred under agreements with third parties, such as consultants, contractors, and contract research organizations ("CROs") to conduct preclinical studies and clinical trials;
- the cost of developing and validating our manufacturing process for use in our preclinical studies and clinical trials, including the cost of raw materials used in our research and development activities, and engaging with third party contract manufacturing organizations ("CMOs");
- costs incurred in connection with the performance of research and development activities under the Vertex Agreement;
- the cost of laboratory supplies and research materials;
- the costs of payments made under third-party licensing agreements and related future payments should certain development and regulatory milestones be achieved; and
- facilities, depreciation and other direct and allocated expenses, including rent and other operating costs, incurred as a result of our research and development activities.

We expense research and development costs as incurred. Non-refundable 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. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered. Upfront payments under license agreements are expensed upon receipt of the license and annual maintenance fees under license agreements are expensed in the period in which they are incurred. Milestone payments under license agreements are accrued, with a corresponding expense being

recognized, in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable.

Our research and development costs are primarily devoted to supporting our neuromuscular program development efforts. Our direct, external research and development expenses consist primarily of fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our process development, manufacturing and clinical development activities. Our direct external research and development expenses also include fees incurred under license and intellectual property purchase agreements. Where specifically identifiable, we expect to track these external research and development costs on a program-by-program basis as we identify product candidates to advance into clinical development.

We do not allocate employee costs, costs associated with our development efforts and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources and third-party consultants primarily to conduct our research and development activities as well as for managing our process development, manufacturing and clinical development activities.

Therapeutic candidates in later stages of clinical development 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 platform development efforts and planned preclinical and planned and current clinical development activities in the near term and in the future. We further expect that the research and development expenses of our programs will increase in the near term as we initiate or continue CTA/IND-enabling activities for our therapeutic candidates. Therefore, we cannot reasonably estimate or know the nature, timing, and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our therapeutic candidates. The successful development of our therapeutic candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development, including the following:

- the scope, timing, rate of progress and expenses of our ongoing and potential future research activities, including preclinical and CTA/IND-enabling studies, clinical trials and other research and development activities we decide to pursue;
- the successful initiation, enrollment and completion of clinical trials under current good clinical practices ("GCPs");
- the timing of filing and acceptance of INDs or comparable foreign applications that allow commencement of future clinical trials for our therapeutic candidates;
- whether our therapeutic candidates show safety and efficacy in our clinical trials and an acceptable risk-benefit profile in the intended populations;
- our ability to hire and retain key research and development personnel to meet our strategic goals;
- our ability to successfully develop, obtain regulatory and marketing approvals of our therapeutic candidates for the expected indications and patient populations;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our therapeutic candidates are approved;
- commercializing therapeutic candidates, if and when approved, whether alone or in collaboration with others;
- our ability to maintain a continued acceptable safety, tolerability and efficacy profile of our therapeutic candidates following approval;
- our ability to establish new licensing or collaboration arrangements to support our potential therapeutic candidates on favorable business terms;
- any decisions we make to discontinue, delay or modify our programs to focus on others;
- obtaining, maintaining, protecting and enforcing patent and trade secret protection and regulatory exclusivity for our therapeutic candidates; and
- obtaining and maintaining adequate coverage and reimbursement from third party payors.

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

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and personnel-related costs, including stock-based compensation, for our personnel in executive, legal, finance and accounting, corporate and business development, human resources and other administrative functions. General and administrative expenses also include: legal fees relating to intellectual property and corporate matters; professional fees paid for accounting, auditing, consulting and tax services; insurance costs; travel expenses; information technology expenses; and facility costs not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount and expand our facilities to support our continued research activities and development of our programs and our EEV platform ("EEV Platform").

Interest and Other Income (Expense)

Interest and other income (expense) consists primarily of interest earned on our invested cash equivalents and marketable securities, gains and losses on disposal of fixed assets and gains and losses on foreign currency transactions.

Income Taxes

Provision for income tax expense (benefit) recorded in any interim period is based on the estimated effective tax rate for the fiscal year for those tax jurisdictions that can be reliably estimated. There were no significant income tax provisions or benefits recorded for the three and nine months ended September 30, 2026. The Company recorded income tax expense of $0.7 million for the three months ended September 30, 2025 and $0.8 million for the nine months ended September 30, 2025. For the three and nine months ended September 30, 2025, the income tax provision recorded was primarily driven by adjustments made upon the finalization of tax returns.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and estimates from those reported in the Annual Report, except as described further in Note 2 *Summary of Significant Accounting Policies* in the condensed consolidated financial statements elsewhere in this Quarterly Report.

Results of Operations

Comparison of the three months ended September 30, 2026 and 2025

(in thousands)	Three Months Ended September 30, 2026	2025	Change
Collaboration revenue	$ 905	$ 1,614	$ (709)
Operating expenses:			
Research and development	32,369	38,361	(5,992)
General and administrative	10,225	10,304	(79)
Total operating expenses	42,594	48,665	(6,071)
Loss from operations	(41,689)	(47,051)	5,362
Other income:			
Interest and other income	1,974	3,571	(1,597)
Total other income	1,974	3,571	(1,597)
Loss before provision for income taxes	(39,715)	(43,480)	3,765
Provision for income taxes	27	654	(627)
Net loss	$ (39,742)	$ (44,134)	$ 4,392

Collaboration Revenue

Collaboration revenue was $0.9 million for the three months ended September 30, 2026 and $1.6 million for the three months ended September 30, 2025.

Research and Development Expenses

(in thousands)	Three Months Ended September 30, 2026	2025	Change
Direct research and development expenses			
ENTR-601-44	$ 6,245	$ 6,568	$ (323)
ENTR-601-45	4,467	3,543	924
ENTR-601-50	254	3,164	(2,910)
ENTR-601-51	794	2,807	(2,013)
DMD franchise-wide[(1)]	1,475	883	592
Collaboration services	293	534	(241)
Ocular programs	863	791	72
Other preclinical and discovery	511	490	21
Unallocated research and development expenses			
Personnel related (including stock-based compensation)	11,948	11,549	399
Facility related and other	5,519	8,032	(2,513)
Total research and development expenses	$ 32,369	$ 38,361	$ (5,992)

(1) Represents manufacturing and clinical costs that support across the Company's product candidates targeting DMD.

Research and development expenses were $32.4 million for the three months ended September 30, 2026, compared to $38.4 million for the three months ended September 30, 2025. The decrease of $6.0 million in research and development expenses was primarily attributable to:

- a decrease of $3.9 million in direct research and development expenses, primarily driven by lower preclinical costs for the Company's Duchenne programs; and
- a decrease of $2.1 million in unallocated research and development expenses, primarily driven by a decrease in facility related and other costs of $2.5 million, offset by an increase in personnel costs of $0.4 million. Personnel costs are inclusive of stock-based compensation expense of $2.3 million for the three months ended September 30, 2026 and 2025.

We expect that our research and development expenses will increase as we continue to advance our Duchenne franchise through clinical trials, advance our ocular programs through preclinical development and into clinical trials and continue to perform discovery work for future product candidates.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2026 were $10.2 million, compared to $10.3 million for the three months ended September 30, 2025.

Interest and Other Income

Total interest and other income was $2.0 million for the three months ended September 30, 2026, compared to $3.6 million of interest and other income for the three months ended September 30, 2025. The decrease was driven by changes in interest earned from debt securities and money market funds as well as a decrease in the amount of marketable securities held.

Comparison of the nine months ended September 30, 2026 and 2025

	Nine Months Ended September 30,		
(in thousands)	**2026**	**2025**	**Change**
Collaboration revenue	$ 2,678	$ 24,122	$ (21,444)
Operating expenses:			
Research and development	100,792	108,312	(7,520)
General and administrative	30,841	31,500	(659)
Total operating expenses	131,633	139,812	(8,179)
Loss from operations	(128,955)	(115,690)	(13,265)
Other income:			
Interest and other income	6,833	11,936	(5,103)
Total other income	6,833	11,936	(5,103)
Loss before provision for income taxes	(122,122)	(103,754)	(18,368)
Provision for income taxes	100	832	(732)
Net loss	$ (122,222)	$ (104,586)	$ (17,636)

Collaboration Revenue

Collaboration revenue was $2.7 million for the nine months ended September 30, 2026 and $24.1 million for the nine months ended September 30, 2025. The decrease of $21.4 million was primarily a result of us substantially completing our research plan activities for VX-670 during the first quarter of 2025. We continue to perform research activities on additional EEV-based therapeutic candidates for the potential treatment of DM1 pursuant to the Vertex Agreement.

Research and Development Expenses

(in thousands)	Nine Months Ended September 30, 2026	2025	Change
Direct research and development expenses			
ENTR-601-44	$ 18,213	$ 15,748	$ 2,465
ENTR-601-45	11,098	10,978	120
ENTR-601-50	3,350	5,896	(2,546)
ENTR-601-51	4,391	6,488	(2,097)
DMD franchise-wide[(1)]	6,700	2,595	4,105
Collaboration services	828	1,937	(1,109)
Ocular programs	1,973	1,603	370
Other preclinical and discovery	1,517	2,159	(642)
Unallocated research and development expenses			
Personnel related (including stock-based compensation)	35,785	37,536	(1,751)
Facility related and other	16,937	23,372	(6,435)
Total research and development expenses	$ 100,792	$ 108,312	$ (7,520)

(1) Represents manufacturing and clinical costs that support across the Company's product candidates targeting DMD.

Research and development expenses were $100.8 million for the nine months ended September 30, 2026, compared to $108.3 million for the nine months ended September 30, 2025. The decrease of $7.5 million in research and development expenses was primarily attributable to:

- a decrease of $8.2 million in unallocated research and development expenses driven by a decrease in facility related and other costs of $6.4 million and a decrease in personnel costs of $1.8 million. Personnel costs are inclusive of stock-based compensation expense of $6.9 million and $6.8 million for the nine months ended September 30, 2026 and 2025, respectively; and

- an increase of $0.7 million in direct research and development expenses, driven by higher clinical and manufacturing costs for our Duchenne programs, partially offset by lower preclinical costs for our Duchenne programs and lower costs related to our collaboration with Vertex and other preclinical and discovery activities.

We expect that our research and development expenses will increase as we continue to advance our Duchenne franchise through clinical trials, advance our ocular programs through preclinical development and into clinical trials and continue to perform discovery work for future product candidates.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2026 were $30.8 million, compared to $31.5 million for the nine months ended September 30, 2025. The decrease of $0.7 million was primarily attributable to a decrease in professional services.

Interest and Other Income

Total interest and other income was $6.8 million for the nine months ended September 30, 2026, compared to $11.9 million of interest and other income for the nine months ended September 30, 2025. The decrease was driven by changes in interest earned from debt securities and money market funds as well as a decrease in the amount of marketable securities held.

Liquidity and Capital Resources

Overview

Since our inception, we have devoted substantially all our resources to research and development efforts relating to our EEV Platform, advancing development of our portfolio of genetic medicines for the potential treatment of neuromuscular and inherited retinal diseases and administrative support for these operations, including raising capital.

Since inception, we have incurred significant net losses and we expect to continue to generate operating losses and negative operating cash flows for the foreseeable future as we advance our platform and therapeutic candidates. As of September 30, 2026, we had an accumulated deficit of $395.3 million. We will not generate any revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more therapeutic candidates, if ever. If we obtain regulatory approval for any therapeutic candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution.

We expect that our cash, cash equivalents and marketable securities of $193.0 million as of September 30, 2026 will be sufficient to fund our operations and capital expenditure requirements into the fourth quarter of 2027. This estimate is based on our current operating plan and excludes the potential effects of any future financing events or milestone payments that may be received under the Vertex Agreement. These conditions raise substantial doubt about our ability to continue as a going concern within 12 months from the date these condensed consolidated financial statements are issued.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy, as we advance therapeutic candidates through preclinical and, if successful, into clinical development, seek regulatory approval, prepare for and, if any therapeutic candidates are approved, proceed to commercialization and operate as a public company. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions.

If we are unable to obtain funding, we will be forced to delay, reduce, or eliminate some or all of our research and development programs, product portfolio expansion and ultimate commercialization efforts, which would adversely affect our business prospects, or we may be unable to continue operations. Although we continue to pursue these plans, we may not be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

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. Even if we can generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Sources of Liquidity

To date, we have raised over $850.0 million of gross proceeds from sales of stock to leading biotechnology investors and from the Vertex Agreement. As of September 30, 2026, we had cash, cash equivalents and marketable securities of $193.0 million.

In November 2025, we entered into a sales agreement (the "Sales Agreement"), with TD Securities (USA) LLC (f/k/a Cowen and Company, LLC), acting as our agent and/or principal (the "Sales Agent"), with respect to an "at the market offering" program under which we may, from time to time, at our sole discretion, issue and sell shares of our common stock having an aggregate offering price of up to $150.0 million through the Sales Agent. During the three months ended September 30, 2026, there have been no sales of common stock pursuant to the Sales Agreement.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

(in thousands)	Nine Months Ended September 30, 2026	2025
Net cash used in operating activities	$ (104,122)	$ (96,309)
Net cash provided by investing activities	124,858	87,689
Net cash provided by financing activities	450	695
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 21,186	$ (7,925)

Operating Activities

For the nine months ended September 30, 2026, net cash used in operating activities was $104.1 million and was driven by our net loss of $122.2 million, net cash provided by changes in our operating assets and liabilities of $2.4 million, adjustments for non-cash expenses relating to stock-based compensation expense of $14.7 million and depreciation expense of $2.3 million, and adjustments for non-cash income relating to accretion of premiums and discounts of $1.3 million.

For the nine months ended September 30, 2025, net cash used in operating activities was $96.3 million and was driven by our net loss of $104.6 million, net cash used in changes in our operating assets and liabilities of $7.2 million, adjustments for non-cash expenses relating to stock-based compensation expense of $15.3 million and depreciation expense of $3.2 million, and adjustments for non-cash income relating to accretion of premiums and discounts of $3.0 million.

Investing Activities

Net cash provided by investing activities was $124.9 million for the nine months ended September 30, 2026, consisting primarily of $148.8 million from the maturities of marketable securities, partially offset by $23.7 million in purchases of marketable securities and $0.2 million of purchases of property and equipment.

Net cash provided by investing activities was $87.7 million for the nine months ended September 30, 2025, consisting primarily of $212.1 million from the maturities of marketable securities, partially offset by $123.1 million in purchases of marketable securities and $1.3 million of purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $0.5 million for the nine months ended September 30, 2026, consisting of $0.2 million in proceeds from stock option exercises and $0.3 million from the issuance of common stock under our 2021 Employee Stock Purchase Plan, as amended (the "2021 ESPP").

Net cash provided by financing activities was $0.7 million for the nine months ended September 30, 2025, consisting of $0.4 million in proceeds from stock option exercises and $0.3 million from the issuance of common stock under the 2021 ESPP.

Future Funding Requirements

We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our programs. Our operating expenses and future funding requirements are expected to increase substantially as we continue to advance our portfolio of programs. We expect that our cash, cash equivalents and marketable securities of $193.0 million as of September 30, 2026 will be sufficient to fund our operations and capital expenditure requirements into the fourth quarter of 2027.

Because of the numerous risks and uncertainties associated with research, development, and commercialization of our candidates, we are unable to estimate the exact amount of our working capital requirements. Our future capital requirements will depend on many factors, including costs associated with:

- the continuation of our current research programs and our clinical and preclinical development of therapeutic candidates from our current research programs;
- advancing our existing and future therapeutic candidates into clinical development;
- initiating preclinical studies and clinical trials for any therapeutic candidates we identify and develop or expand development of existing programs into additional indications;
- maintaining, expanding, enforcing, defending and protecting our intellectual property portfolio and providing reimbursement of third-party expenses related to our patent portfolio;
- timing of manufacturing for our therapeutic candidates and commercial manufacturing if any therapeutic candidate is approved;
- establishing and maintaining clinical and commercial supply for the development and manufacture of our therapeutic candidates;
- seeking regulatory and marketing approvals for any of our therapeutic candidates that we develop, if any;
- seeking to identify, establish and maintain additional collaborations and license agreements, and the success of those collaborations and license agreements;
- ultimately establishing a sales, marketing and distribution infrastructure to commercialize any platforms for which we may obtain marketing approval, either by ourselves or in collaboration with others;
- generating revenue from commercial sales of therapeutic candidates we may develop for which we receive marketing approval;
- hiring additional personnel, including research and development, clinical and commercial personnel, to meet our strategic goals;
- adding operational, financial and management information systems and personnel, including personnel to support our product development;
- achieving sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- acquiring or in-licensing products, intellectual property, and technologies; and
- the ongoing costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenue to support our cost structure, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise funds through collaborations or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or therapeutic candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our therapeutic candidates even if we would otherwise prefer to develop and market such therapeutic candidates ourselves.

Contractual Obligations and Commitments

Lease Commitments

During the nine months ended September 30, 2026, there were no material changes to our lease commitments from those described in Note 11, *Leases,* of our financial statements in the Annual Report.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs, third-party manufacturers, and other third parties for preclinical research studies and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancellable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation.

We have also entered into license agreements under which we are obligated to make certain payments. During the nine months ended September 30, 2026, there were no material changes to our commitments and contingencies related to our license agreements from those described in "Business—Intellectual property— License agreement with The Ohio State University" and Note 11, *Commitments and Contingencies,* to our financial statements in the Annual Report. For additional information regarding our license agreements, refer to Note 11, *Commitments and Contingencies,* to our condensed consolidated financial statements in this Quarterly Report.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" ("EGC") under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Section 107 of the JOBS Act provides that an EGC can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (the "Securities Act"), for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of delayed adoption of new or revised accounting standards and, therefore, we will be subject to the same requirements to adopt new or revised accounting standards as private entities. Upon ceasing to be an EGC, we will be required to adopt any such deferred standards as of the effective dates applicable to public companies.

As an EGC, we may, and intend to, take advantage of certain exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an EGC:

- we may avail ourselves of the exemption from providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act");
- we may avail ourselves of the exemption from complying with any requirement that may be adopted by the Public Company Accounting Oversight Board ("PCAOB") regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis;
- we may provide reduced disclosure about our executive compensation arrangements; and
- we may not require nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments.

We will remain an EGC until the earliest to occur of (i) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering ("IPO"), (ii) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more, (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous rolling three-year period or (iv) the date on which we are deemed to be a large accelerated filer under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Effective as of December 31, 2026, the last day of the fiscal year following the fifth anniversary of the closing of our IPO, we will no longer qualify as an EGC. As a result, commencing with our Annual Report on Form 10-K for the fiscal year ending December 31, 2026, we will no longer be eligible to take advantage of certain exemptions from various reporting requirements that are applicable to EGCs.

We are also a "smaller reporting company" because the market value of our stock held by non-affiliates was less than $250 million as of June 30, 2025. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. Even after we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies for so long as we remain a smaller reporting company. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently Issued Accounting Pronouncements

See Note 2, *Summary of Significant Accounting Policies* to our condensed consolidated financial statements included elsewhere in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial and accounting officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2026. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2026, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, 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) during the quarter ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

From time to time, claims are made against the Company in the ordinary course of business, which could result in litigation. Claims and associated litigation are subject to inherent uncertainties, and unfavorable outcomes could occur. In the opinion of management, the resolution of these matters, if any, will not have a material adverse impact on the Company's financial position or results of operations.

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 ("Quarterly Report") and in other documents that we file with the Securities and Exchange Commission ("SEC"). Investing in our common stock involves a high degree of risk. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline and you could lose part or all of your investment. Unless otherwise indicated, reference in this section and elsewhere in this Quarterly Report to our business being adversely affected, negatively impacted or harmed will include an adverse effect on, or a negative impact or harm to, the business, reputation, financial condition, results of operations, revenue and our future prospects. The material and other risks and uncertainties summarized above and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Quarterly Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See the section titled "Cautionary Note Regarding Forward-Looking Statements."

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue from product sales or become profitable or, if we achieve profitability, we may not be able to sustain it.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a limited operating history upon which our stockholders can evaluate our business and prospects. While our programs for ENTR-601-44, ENTR-601-45, ENTR-601-50, ENTR-601-51 and our partnered candidate VX-670 are in the clinical development stage or have completed Investigational New Drug application ("IND") and/or Clinical Trial Application ("CTA")-enabling studies, we have additional programs in the preclinical development or in the drug discovery stage. We commenced operations in 2016, and to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, developing our proprietary, highly versatile and modular Endosomal Escape Vehicle ("EEV") platform ("EEV Platform"), identifying therapeutic candidates, establishing our intellectual property portfolio and conducting research and preclinical studies. Our approach to the discovery and development of therapeutic candidates that are based on our EEV Platform is unproven, and we do not know whether we will be able to conduct clinical studies on any of our therapeutic candidates beyond ENTR-601-44, ENTR-601-45 and our partnered candidate VX-670, develop any therapeutic candidates that succeed in clinical development or produce products of commercial value. As an organization, we have only completed a Phase 1 clinical trial of ENTR-601-44 in healthy volunteers in the UK and the MAD portion of the first cohorts of Phase 1/2 clinical trials in the UK and the EU for ENTR-601-44 and ENTR-601-45, and we have not completed the clinical development of any therapeutic candidate nor have we obtained any regulatory approvals, manufactured a commercial-scale product, or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant operating losses since our inception. We do not have any products approved for sale and have not generated any product revenue since our inception. If our therapeutic candidates are not successfully developed and approved, we may never generate any significant revenue from product sales. We have incurred significant net losses since inception. As of September 30, 2026, we had an accumulated deficit of $395.3 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our therapeutic candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate

these losses will increase substantially as we continue our development of, seek regulatory approval for and potentially commercialize any of our therapeutic candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our therapeutic candidates, identifying lead therapeutic candidates, discovering additional therapeutic candidates, conducting preclinical studies prior to submitting an IND and/or CTA, obtaining clearance for INDs/CTAs, obtaining regulatory approval for these therapeutic candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may not succeed in completing necessary activities and regulatory approvals necessary to bring a product to market and, even if we do, may never generate revenues that are significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even 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 may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our therapeutic candidates or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

Our limited operating history may make it difficult to evaluate our technology and industry and predict our future performance. Though several groups have conducted or are conducting studies involving the intracellular delivery of therapeutic molecules, the relevance of those studies to the evaluation of therapeutic candidates developed using our EEV Platform may be difficult to ascertain. Our short history as an operating company and novel therapeutic approach make any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by earlier stage companies in rapidly evolving fields. Failure to address these risks successfully will cause our business to suffer. Similarly, we expect that our financial condition and operating results will fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, our stockholders should not rely upon the results of any quarterly or annual period as an indicator of future operating performance.

In addition, as an early clinical-stage company, we have encountered unforeseen expenses, difficulties, complications, delays and other known and unknown circumstances. As we advance our therapeutic candidates, we will need to continue our transition from a company with a research focus to a company supporting clinical development and if successful, capable of supporting commercial activities. We may not continue to be successful in our transition.

We will require additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.

The development of biopharmaceutical therapeutic candidates is capital-intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned preclinical studies of our development programs, continue to initiate clinical trials for our therapeutic candidates and seek regulatory approval for our current therapeutic candidates and any future therapeutic candidates we may develop. If we obtain regulatory approval for any of our therapeutic candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our therapeutic candidates. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Failing to raise capital when needed or on attractive terms could force us to delay, reduce or eliminate our research and development programs or any future commercialization efforts. Based on our current operating plans, we believe that our cash, cash equivalents and marketable securities as of September 30, 2026 will be sufficient to fund our operations and capital expenditure requirements into the fourth quarter of 2027, but not for at least 12 months from the date the condensed consolidated financial statements included in this Quarterly Report are issued. As a result, there is substantial doubt about our ability to continue as a going concern. See "—We have identified conditions that raise substantial doubt about our ability to continue as a going concern" below. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially additional collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds

for our current or future operating plans. For example, in November 2025, we entered into a sales agreement (the "Sales Agreement") with TD Securities (USA) LLC (f/k/a Cowen and Company, LLC) acting as our agent and/or principal (the "Sales Agent"), with respect to an "at the market offering" program under which we may offer and sell, from time to time, at our sole discretion, shares of common stock having an aggregate offering price of up to $150.0 million through the Sales Agent. However, there can be no assurance that the Sales Agent will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate, and the substantial doubt about our ability to continue as a going concern may make it more difficult to raise capital on acceptable terms, or at all. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our therapeutic candidates. Our future capital requirements will depend on many factors, including, but not limited to:

- the type, number, scope, progress, expansions, results, costs and timing of our preclinical studies and any clinical trials of the therapeutic candidates that we are pursuing or may choose to pursue in the future;
- the clinical development plans we establish for our therapeutic candidates;
- the costs and timing of manufacturing for our therapeutic candidates and commercial manufacturing if any therapeutic candidate is approved;
- the costs of establishing and maintaining clinical and commercial supply for the development and manufacture of our therapeutic candidates;
- the costs, timing and outcome of regulatory review of our therapeutic candidates;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements, if any;
- the costs and timing of establishing or securing sales and marketing capabilities if any therapeutic candidate is approved;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our therapeutic candidates;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the ongoing costs of operating as a public company.

Identifying potential therapeutic candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and commercialize our therapeutic candidates. In addition, our therapeutic candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

We have identified conditions that raise substantial doubt about our ability to continue as a going concern. If we fail to obtain additional financing or cannot obtain financing at the levels we require, we may be forced to delay, reduce or discontinue our plans and operations or unable to complete the development and commercialization of our product candidates.

The accompanying unaudited condensed consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to our

ability to continue as a going concern. We have had no revenues from product sales and have incurred operating losses since inception. We expect to continue to incur significant expenses in connection with the development of our product candidates and, if approved, their commercialization. Based on our current operating plans, we believe that our cash, cash equivalents and marketable securities as of September 30, 2026 will be sufficient to fund our operations and capital expenditure requirements into the fourth quarter of 2027, but not for at least 12 months from the date the condensed consolidated financial statements included in this Quarterly Report are issued. As a result, there is substantial doubt about our ability to continue as a going concern. Our estimates of future cash requirements are based on assumptions that may prove incorrect, and we may need additional capital sooner than currently anticipated. We will need additional financing to pursue our business strategy and may pursue additional cash resources through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing or other arrangements. There is no assurance that we will be successful in obtaining sufficient funding on acceptable terms, if at all.

We may also encounter business endeavors that require significant cash commitments or unanticipated problems or expenses that could result in a requirement for additional cash. If we raise additional funds through the issuance of equity or convertible debt securities in the future, the percentage ownership of our current stockholders could be reduced, and such securities might have rights, preferences or privileges senior to our common stock. Additional financing may not be available upon acceptable terms, or at all. If adequate funds are not available or are not available on acceptable terms, we may be forced to delay, reduce or discontinue our research and development programs or clinical trials, limit our operations or forgo potential business opportunities, which could significantly and materially restrict our operations.

Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our programs, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current therapeutic candidates and any future therapeutic candidates, which may vary depending on the U.S. Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA") or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional therapeutic candidates and technologies or other assets;
- the timing and outcomes of preclinical studies and clinical trials for ENTR-601-44, ENTR-601-45, ENTR-601-50, ENTR-601-51, ENTR-801, our partnered candidate VX-670 and any therapeutic candidates from our discovery programs, or competing therapeutic candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;

- competition from existing and potential future products that compete with ENTR-601-44, ENTR-601-45, ENTR-601-50, ENTR-601-51, ENTR-801, our partnered candidate VX-670 or any of our discovery programs, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of ENTR-601-44, ENTR-601-45, ENTR-601-50, ENTR-601-51, ENTR-801, our partnered candidate VX-670 or therapeutic candidates from any of our discovery programs;
- the level of demand for any of our therapeutic candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our therapeutic candidates, if approved, and existing and potential future products that compete with ENTR-601-44, ENTR-601-45, ENTR-601-50, ENTR-601-51, ENTR-801, our partnered candidate VX-670 or any of our discovery programs;
- our or our partners' ability to commercialize ENTR-601-44, ENTR-601-45, ENTR-601-50, ENTR-601-51, ENTR-801, our partnered candidate VX-670 or therapeutic candidates from any of our discovery programs, if approved, inside and outside of the U.S., either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile U.S. and global economic and political environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

Risks Related to the Discovery, Development and Regulatory Approval of Our Therapeutic Candidates

We are early in our development efforts and as a result it will be years before we commercialize a therapeutic candidate, if ever. If we are unable to identify and advance therapeutic candidates through preclinical studies and/or clinical trials, obtain marketing approval and ultimately commercialize them, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts and all our development programs, including our lead therapeutic candidates ENTR-601-44, ENTR-601-45, our clinic ready candidates ENTR-601-50 and ENTR-601-51, our partnered candidate VX-670, and ENTR-801, which is in the preclinical stage. We have invested substantially all of our research efforts to date in developing our EEV Platform, identifying potential therapeutic candidates, conducting preclinical studies, and initiating early clinical studies. As an organization, we have only completed a Phase 1 clinical trial of ENTR-601-44 in healthy volunteers in the UK and the MAD portion of the first cohorts of Phase 1/2 clinical trials in the UK and the EU for ENTR-601-44 and ENTR-601-45, and we have not completed the clinical development of any therapeutic candidate nor have we submitted an application for regulatory approval, and we may be unable to do so for our therapeutic candidates. We have completed CTA/IND-enabling studies for ENTR-601-44, ENTR-601-45, ENTR-601-50, ENTR-601-51 and VX-670; however, we will need to complete CTA/IND-enabling studies for our other product candidates to support their progression into and/or through clinical studies in the United States and elsewhere. In addition, we have a development portfolio of programs that are in earlier stages of development and have not yet initiated or completed IND-enabling studies. We may never advance any additional therapeutic candidates through IND-enabling studies and receive authorization from the FDA, to proceed under an IND prior to initiating their clinical-stage development. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our therapeutic candidates, which may never occur. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND and finalizing the trial design based on discussions with the FDA and other regulatory authorities. For the FDA to accept an IND, we must complete Good Laboratory Practices ("GLP") studies, which may not be successful or may take longer than we expect. The FDA may require us to complete additional preclinical studies or we may be required to satisfy other FDA requests prior to commencing clinical trials in the United States, and such requests may not currently be known or anticipated, which may cause the start of our clinical trials to be delayed in the United States or prevent us from conducting clinical trials in the

United States. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials, impose stricter approval conditions than we currently expect or may prevent us from conducting clinical trials. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union ("EU") and the United Kingdom ("UK").

Commercialization of any therapeutic candidates we may develop will require preclinical and clinical development; regulatory and marketing approval in each jurisdiction targeted for commercialization, including by the FDA, the EMA and the United Kingdom Medicines and Healthcare Products Regulatory Agency ("MHRA"); manufacturing supply, capacity and expertise; a commercial organization; and significant marketing efforts. The success of therapeutic candidates we may identify and develop will depend on many factors, including:

- timely and successful completion of preclinical studies, including toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, where applicable;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- effective INDs, CTAs or other comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for any therapeutic candidates we may develop;
- successful enrollment and completion of clinical trials, including under the FDA's current Good Clinical Practices ("GCPs"), GLPs and any additional regulatory requirements from foreign regulatory authorities, such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice;
- positive results from our current and future clinical trials that support a finding of safety and effectiveness and an acceptable risk-benefit profile in the intended populations;
- receipt of regulatory marketing approvals from applicable regulatory authorities;
- establishment of arrangements with third-party manufacturers for clinical supply and, where applicable, commercial manufacturing capabilities;
- establishment, maintenance, defense and enforcement of patent, trademark, trade secret and other intellectual property protection or regulatory exclusivity for any therapeutic candidates we may develop;
- patient recruitment and enrollment;
- commercial launch of any therapeutic candidates we may develop, if approved, whether alone or in collaboration with others;
- acceptance of the benefits and use of our therapeutic candidates we may develop, including method of administration, if and when approved, by patients, the medical community and third-party payors;
- our ability to compete effectively with other therapies and treatment options;
- maintenance of a continued acceptable safety, tolerability and efficacy profile of any therapeutic candidates we may develop following approval; and
- establishment and maintenance of healthcare coverage and adequate reimbursement by payors.

If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any therapeutic candidates we may develop, which would materially harm our business. If we are unable to advance our therapeutic candidates to clinical development, obtain regulatory approval and ultimately commercialize our therapeutic candidates, or experience significant delays in doing so, our business will be materially harmed.

Our business is highly dependent on the clinical advancement of our programs and modalities and is especially dependent on the success of our lead therapeutic candidates, ENTR-601-44 and ENTR-601-45, as well as ENTR-601-50, ENTR-601-51, ENTR-801 and our partnered candidate VX-670. Delay or failure to advance programs or modalities, including ENTR-601-44, ENTR-601-45, ENTR-601-50, ENTR-601-51, ENTR-801 and VX-670 could adversely impact our business.

Using our platform, we are developing product features for medicines based on EEV peptides. Over time, our platform work led to commonalities, where a specific combination of EEV technologies, delivery technologies, and manufacturing processes generated a set of product features shared by multiple programs, for example, oligonucleotide- and protein-conjugated EEV peptides. This is what we call a "modality." We are utilizing early programs in a modality, such as ENTR-601-44 for oligonucleotide-conjugated EEV peptides, to understand the technology risks within the

modality, including manufacturing and pharmaceutical properties. Our lead therapeutic candidates ENTR-601-44 and ENTR-601-45 are being developed to address DMD, and we are highly dependent on the success of the current and future clinical trials of ENTR-601-44 and ENTR-601-45, the outcomes of which are uncertain, to further develop ENTR-601-50, our therapeutic candidate for patients with DMD who are exon 50 skipping amenable and ENTR-601-51, our therapeutic candidate for patients with DMD who are exon 51 skipping amenable. Because ENTR-601-44 is our EEV therapeutic candidate furthest along in clinical development, if ENTR-601-44 encounters safety, efficacy, supply or manufacturing problems, developmental delays, regulatory or commercialization issues or other problems, the value of our EEV Platform, including our other therapeutic candidates such as ENTR-601-45, ENTR-601-50, ENTR-601-51 and our partnered candidate VX-670, could be greatly diminished and our development plans and business would be significantly harmed.

Even if our earlier programs in a modality are successful in any phase of development any of such earlier programs may fail at a later phase of development, and other programs within the same modality may still fail at any phase of development including at phases where earlier programs in that modality were successful. This may be a result of technical challenges unique to that program or due to biology risk, which is unique to every program. As we progress our programs through clinical development, there may be new technical challenges that arise that cause an entire modality to fail.

Our EEV therapeutic candidates are based on a novel therapeutic approach, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all.

Using EEV technology to develop therapeutic candidates is a new therapeutic approach and no products based on EEV peptides have been approved to date in the United States or the rest of the world. As such, it is difficult to accurately predict the developmental challenges we may face for our EEV therapeutic candidates as they proceed through development. As an organization, we have only completed a Phase 1 clinical trial of ENTR-601-44 in healthy volunteers in the UK and the MAD portion of the first cohorts of Phase 1/2 clinical trials in the UK and the EU for ENTR-601-44 and ENTR-601-45 and have not yet completed any clinical trials with our other therapeutic candidates. We have only limited data assessing safety of our approach in humans, and there may be short-term or long-term effects from treatment with any therapeutic candidates that we develop that we cannot predict at this time. Also, animal models may not exist for some of the diseases we choose to pursue in our programs. As a result of these factors, it is more difficult for us to predict the time and cost of therapeutic candidate development and we cannot predict whether our EEV Platform, or any similar or competitive intracellular delivery technologies, will enable the identification, development and regulatory approval of any products. There can be no assurance that any development problems we experience in the future related to our EEV Platform or any of our research programs will not cause significant delays or unanticipated costs or that such development problems can be solved. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we have initiated or may initiate or commercializing any therapeutic candidates we may develop on a timely or profitable basis, if at all.

The clinical trial requirements of the FDA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a therapeutic candidate vary substantially according to the type, complexity, novelty and intended use and market of the therapeutic candidate. No products based on EEV peptides have been approved to date by regulators. As a result, the regulatory approval process for therapeutic candidates such as ours is uncertain and may be more expensive and take longer than the approval process for therapeutic candidates based on other, better known or more extensively studied technologies. For example, the general approach for FDA approval of a new biologic or drug is for sponsors to seek licensure or approval based on dispositive data from well-controlled, Phase 3 clinical trials of the relevant therapeutic candidate in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our therapeutic candidates in the U.S., the UK, or other regions of the world or how long it will take to commercialize our therapeutic candidates. Delay or failure to obtain or unexpected costs in obtaining the regulatory approvals necessary to bring a potential therapeutic candidate to market could decrease our ability to generate sufficient product revenue and our business, financial condition, results of operations and prospects may be harmed.

Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies are not necessarily predictive of the results of later preclinical studies and any clinical trials of our therapeutic candidates. We have not yet completed the testing of any of our therapeutic candidates in clinical trials and our therapeutic candidates may not have favorable results in clinical trials or receive regulatory approval on a timely basis, if at all.

Preclinical and clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that our preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. Any positive results from our preclinical studies of our therapeutic candidates may not necessarily be predictive of the results in later preclinical studies and clinical trials. Similarly, even if we are able to complete our current or planned preclinical

studies or clinical trials of our therapeutic candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials may not be replicated in our subsequent preclinical studies or later-stage clinical trials. Despite promising preclinical or clinical results, any therapeutic candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for therapeutic candidates in our industry is high.

The results from preclinical studies or clinical trials of a therapeutic candidate may not predict the results of later clinical trials of the therapeutic candidate, and interim, topline, or preliminary results of a clinical trial are not necessarily indicative of final results. Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while we have completed certain preclinical studies of our therapeutic candidates, a healthy normal volunteer study and one multi-ascending dose cohort in patients for ENTR-601-44 and ENTR-601-45, respectively, we do not know whether these therapeutic candidates will perform in current or future clinical trials as they have performed in these prior studies. The positive results we have observed for our therapeutic candidates in early, non-GLP preclinical studies and animal models may not be predictive of our current or future clinical trials in humans. Furthermore, for some indications that we are pursuing there are no animal models that adequately mirror the human disease to predict any level of positive results. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many therapeutic candidates fail in clinical trials despite very promising early results. Unexpected observations or toxicities observed in our IND-enabling studies for example, could delay clinical trials for ENTR-601-50, ENTR-601-51, ENTR-801 or our other development programs. Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and companies that have believed their therapeutic candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain FDA approval. Additionally, we are utilizing both a blinded multi-ascending dose portion and an "open-label" portion in our ongoing clinical studies of ENTR-601-44 and ENTR-601-45 and may also do so for future clinical trials. In the ENTR-601-44 Phase 1/2 trial, patients from Cohort 1 have now completed both the double blind placebo control dosing regimen and a 6 dose open-label regimen where all participants were administered the therapeutic candidate. Similarly, all of the ENTR-601-45 Phase 1/2 Cohort 1 patients have enrolled in a 6 dose open-label regimen where all participants are administered the therapeutic candidate. The open-label period may be subject to various limitations that may exaggerate any therapeutic effect as patients are aware that they are receiving the experimental treatment and physicians are aware that all the patients are receiving the experimental treatment. Reported outcomes may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, reported outcomes may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials, being aware that all patients have received treatment, may interpret the information more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our therapeutic candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

For the foregoing reasons, we cannot be certain that our ongoing and planned preclinical studies and current and planned clinical trials will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our therapeutic candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

Substantial delays in the commencement, enrollment or completion of our planned clinical trials, or failure to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities could prevent us from commercializing any therapeutic candidates we determine to develop on a timely basis, if at all.

The risk of failure in developing therapeutic candidates is high. It is impossible to predict when or if any therapeutic candidate would prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any therapeutic candidate, we must complete preclinical development, submit an IND or foreign equivalent to permit initiation of clinical studies, and then conduct extensive clinical trials to demonstrate the safety and efficacy of therapeutic candidates in humans. As an organization, we submitted an IND for ENTR-601-44 in the fourth quarter of 2022 which was subsequently placed on clinical hold until February 2025. Although we were successful in resolving this clinical hold, there can be no assurance that our ongoing and planned trials will not be placed on clinical hold or voluntarily paused in the future. Any such hold or other delay could impact our ability to complete or initiate our ongoing or planned trials. We have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted a New Drug Application ("NDA"), Biologics License Application ("BLA") or other comparable foreign regulatory submission for any therapeutic candidate. In addition, we have had limited interactions with the FDA and comparable foreign regulatory authorities and cannot be certain how many clinical trials of ENTR-601-44, ENTR-601-45, ENTR-601-50, ENTR-601-51, ENTR-801, our partnered candidate VX-670 or any other therapeutic candidates will be required or how such trials should be designed. Consequently, we and our partner may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to approval of any of our therapeutic candidates. Clinical trials may fail to demonstrate that our

therapeutic candidates are safe for humans and effective for indicated uses. Even if the clinical trials are successful, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application.

Before we can commence clinical trials for a therapeutic candidate, we must complete extensive preclinical testing and studies that support our INDs and other regulatory filings. We cannot be certain of the timely identification of a therapeutic candidate or the completion or outcome of our preclinical testing and studies and cannot predict whether the FDA or other comparable regulatory authorities will accept our proposed clinical programs or whether the outcome of our preclinical testing and studies will ultimately support the further development of any therapeutic candidates. Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. As a result, we cannot be sure that we will be able to submit INDs or foreign equivalents for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of such applications will result in the FDA or other regulatory authority allowing clinical trials to begin. In addition, if our efforts in the United States and elsewhere are not successful, we may not be able to complete a clinical development program that enables the approval and marketing of our therapeutic candidates as planned, or at all. Furthermore, therapeutic candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, but not limited to, flaws in trial design, dose selection issues, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits.

Other events that may prevent successful enrollment, initiation or timely completion of clinical development include:

- we may be unable to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations ("CROs") and clinical trial sites;
- delays in opening clinical trial sites or obtaining required institutional review board ("IRB") or independent ethics committee approval, or the equivalent review groups for sites outside the United States, at each clinical trial site;
- we may need to add new or additional clinical trial sites;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event or after an inspection of our clinical trial operations or trial sites;
- negative or inconclusive results observed in clinical trials, including failure to demonstrate statistical significance, safety, purity or potency, which could lead us, or cause regulators to require us, to conduct additional clinical trials or abandon product development programs;
- positive results from our preclinical studies of our therapeutic candidates may not necessarily be predictive of the results from required later preclinical studies and clinical trials and positive results from such preclinical studies and clinical trials of our therapeutic candidates may not be replicated in subsequent preclinical studies or clinical trial results;
- failure by us, any CROs we engage or any other third parties to adhere to clinical trial requirements;
- failure to perform in accordance with applicable GCPs;
- failure by investigators to adhere to clinical trial protocols leading to variable results;
- delays in the testing, validation, manufacturing and delivery of any therapeutic candidates we may develop to the clinical sites, including delays by third parties with whom we have contracted to perform certain of those functions;
- failure of our third-party contractors to comply with regulatory requirements or to meet their contractual obligations to us in a timely manner, or at all;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;

- clinical trial sites or patients dropping out of a trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- occurrence of serious adverse events associated with the therapeutic candidate that are viewed to outweigh its potential benefits;
- occurrence of serious adverse events associated with a therapeutic candidate in development by another company, which are viewed to outweigh its potential benefits, and which may negatively impact the perception of our product due to a similarity in technology or approach;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the FDA, other regulatory authorities, or ethics committees may require us to submit additional data such as long-term toxicology studies or impose other requirements before permitting us to initiate a clinical trial;
- changes in the legal or regulatory regimes domestically or internationally related to patient rights and privacy; or
- lack of adequate funding to continue the clinical trial.

After initiating a clinical trial, we could also encounter delays if the clinical trial is suspended, placed on clinical hold or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or other regulatory authorities or recommended for suspension or termination by the Data Safety Monitoring Board ("DSMB") for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our therapeutic candidates. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from preclinical studies, clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their therapeutic candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval.

Any inability to successfully complete preclinical studies and clinical trials could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, manufacturing or formulation changes to any therapeutic candidates we may develop may require us to conduct additional studies or trials to bridge our modified therapeutic candidates to earlier versions. Clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize any therapeutic candidates we may develop or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize any therapeutic candidates we may develop and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of future clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with any therapeutic candidates we may develop, we may:

- be delayed in obtaining marketing approval for therapeutic candidates, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Delays or difficulties in the enrollment of patients in clinical trials could delay or prevent our receipt of necessary regulatory approvals.

Failure to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. may delay or prevent us from initiating or continuing clinical trials for our therapeutic candidates. Because the target patient populations for some of our therapeutic candidates are relatively small, it may be difficult to successfully identify patients. Although we may enter into agreements with third parties to develop companion diagnostic tests for use in some of our future clinical trials in order to help identify eligible patients in certain indications, we may experience delays in reaching, or fail to reach, agreement on acceptable terms to develop such companion diagnostic tests. Any third parties whom we engage to develop companion diagnostic tests may experience delays or may not be successful in developing such companion diagnostic tests, furthering the difficulty in identifying patients for our clinical trials. In addition, current commercially available diagnostic tests to identify appropriate patients for our clinical trials or any approved therapeutic candidates may become unavailable in the future.

Furthermore, some of our competitors have ongoing clinical trials for therapeutic candidates that treat the same indications as our therapeutic candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' therapeutic candidates.

In addition, the pediatric population is an important patient population for certain of the indications we are targeting, including DMD, and our addressable patient population estimates include pediatric populations. However, it may be more challenging to conduct studies in this population, and to locate and enroll pediatric patients. Additionally, it may be challenging to ensure that pediatric or adolescent patients adhere to clinical trial protocols. Patient enrollment and trial competition may be affected by other factors including:

- clinicians' and patients' perceived risks and benefits of the therapeutic candidate under trial, particularly therapeutic candidates developed using a novel and unproven therapeutic approach, like our EEV therapeutic candidates in relation to available or investigational drugs;
- size of the patient population, in particular for rare diseases such as the diseases on which we are initially focused, and process for identifying patients;
- design of the trial protocol;
- efforts to facilitate timely enrollment in clinical trials;
- eligibility and exclusion criteria;
- availability of competing therapies and clinical trials;
- severity of the disease or disorder under investigation;
- proximity and availability of clinical trial sites for prospective patients;
- ability to obtain and maintain patient consent;
- risk that enrolled patients will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

Our inability to identify patients appropriate for enrollment in our clinical trials, or to enroll a sufficient number of patients in our clinical trials, would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our therapeutic candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we are unable to include patients with the driver of the disease, including the applicable genomic alteration for diseases in genomically defined patient populations, this could limit our ability to seek participation in the FDA's expedited development programs, including Breakthrough Therapy Designation and Fast Track Designation, or otherwise to seek to accelerate clinical development and regulatory timelines.

Even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining patients in our clinical trials. In our planned clinical trials that will include a placebo group, some of the patients who end up receiving placebo may perceive that they are not receiving the therapeutic candidate being tested, and they may decide to withdraw from our clinical trials to pursue other alternative therapies rather than continue the trial with the perception that they are receiving placebo. Difficulty enrolling or maintaining a sufficient number of patients to conduct our clinical trials, may require us to delay, limit or terminate clinical trials, any of which would harm our business, financial condition, results of operations and prospects.

Use of our therapeutic candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a therapeutic candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

Although other oligonucleotide therapeutics, enzyme replacement therapies and gene therapies have received regulatory approval, our EEV-based therapeutics are a novel approach to the delivery of biological therapeutics, which may present enhanced uncertainty associated with the safety profile of our therapeutic candidates and other EEV-based therapeutics compared to more well-established classes of therapies. Moreover, it is impossible to predict when or if any therapeutic candidates we may develop will prove safe in humans. As is the case with biopharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our therapeutic candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our therapeutic candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our therapeutic candidates may only be uncovered with a significantly larger number of patients exposed to the therapeutic candidate. Any undesirable side effects or unexpected characteristics associated with our therapeutic candidates in clinical trials may lead us to elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the therapeutic candidate if approved. We may also be required to modify our study plans based on findings after we commence our clinical trials. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test our therapeutic candidates in larger, longer and more extensive clinical trials, or as the use of these therapeutic candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, may be reported by subjects. Any findings of such side effects later in development or upon approval, if any, may harm our business, financial condition and prospects significantly.

Patients treated with our therapeutics, if approved, may experience previously unreported adverse reactions, and it is possible that the FDA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our therapeutic candidates. If safety problems occur or are identified after our therapeutics, if any, reach the market, we may make the decision or be required by regulatory authorities to amend the labeling of our therapeutics, recall our therapeutics or even withdraw approval for our therapeutics.

Our therapeutic candidates are subject to extensive regulation and compliance, which is costly and time-consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our therapeutic candidates.

The clinical development, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, import, export, marketing, distribution and adverse event reporting, including the submission of safety and other information, of our therapeutic candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our therapeutic candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the therapeutic candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a therapeutic candidate for many reasons. For example, the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. Despite the time and expense invested in clinical development of therapeutic candidates, regulatory approval is never guaranteed. Neither we nor any current or future collaborator is permitted to market any of our therapeutic candidates in the United States until we receive approval from the FDA. In February 2026, the then-FDA Commissioner publicly indicated that a single adequate and well-controlled pivotal clinical trial supported by confirmatory evidence would be the FDA's default standard moving forward for novel products, rather than two such trials; this statement was not a formal agency action, and

the scope, implementation and durability of this policy position remain uncertain. In June 2026, the FDA issued revised draft guidance clarifying how sponsors can rely on one scientifically rigorous adequate and well-controlled clinical investigation with confirmatory evidence to satisfy the statutory substantial evidence of effectiveness standard. The FDA retains broad discretion to require additional clinical data for any product candidate, including a second adequate and well-controlled clinical trial.

Prior to obtaining approval to commercialize a therapeutic candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such therapeutic candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our therapeutic candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our therapeutic candidates either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a therapeutic candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our or our current or future collaborators' clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our therapeutic candidates;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we or any of our current or future collaborators may be unable to demonstrate that a therapeutic candidate is safe and effective, and that therapeutic candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our therapeutic candidates are acceptable or sufficient to support the submission of an NDA or BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our therapeutic candidates;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes, approval policies or facilities of our third-party manufacturers with which we or any of our current or future collaborators contract for clinical and commercial supplies;
- regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed biopharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing our therapeutic candidates.

Our approach to the discovery and development of therapeutic candidates that are based on our EEV Platform is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our therapeutic candidates or render our EEV Platform obsolete.

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our proprietary EEV Platform, which leverages a novel and unproven approach. While we have observed favorable preclinical study results based on our EEV Platform, we have not yet succeeded and may not succeed in demonstrating sufficient efficacy and safety to enable the approval of any therapeutic candidates that are based on our EEV Platform as a result of our clinical trials or obtain marketing approval thereafter. Our lead therapeutic candidates, with the exception of ENTR-601-44, ENTR-601-45, ENTR-601-50 and our partnered candidate VX-670, but including ENTR-601-51, have yet to receive authorization to initiate clinical trials and are in preclinical development or in the drug discovery stage. Our research methodology and novel approach to intracellular therapeutics may be unsuccessful in identifying additional therapeutic candidates, and any therapeutic candidates based on our EEV Platform may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the therapeutic candidates unmarketable or unlikely to receive marketing approval. Further, because many of our therapeutic candidates and development programs are based on our EEV Platform, adverse developments with respect to one of these programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs.

In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our EEV approach. Failure to stay at the forefront of technological change in utilizing our EEV Platform to create and develop therapeutic candidates may prevent us from competing effectively. Our competitors may render our EEV approach obsolete, or limit the commercial value of our therapeutic candidates, by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value of our EEV Platform and potential of our therapeutic candidates that are based on our EEV Platform.

The occurrence of any of these events may force us to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Interim, topline and preliminary data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, preliminary or topline data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Topline 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, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim, preliminary or topline data from our clinical studies. Interim, topline or preliminary 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. Adverse differences between preliminary, topline or interim data and final data could significantly harm our business prospects. This would include such adverse differences, should they occur, in connection with our previously disclosed data from Cohort 1 of participants with DMD treated with ENTR-601-44 in our Phase 1/2 ELEVATE-44-201 study, as well as any adverse differences, should they occur, in connection with our previously disclosed data from Cohort 1 of participants with DMD treated with ENTR-601-45 in our Phase 1/2 ELEVATE-45-201 study.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular therapeutic candidate or product and the value of our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial will be based on what is typically extensive information, and our stockholders or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, therapeutic candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our therapeutic candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may expend our limited resources to pursue particular therapeutic candidates or indications, such as our initial focuses on developing ENTR-601-44 and ENTR-601-45, and fail to capitalize on therapeutic candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited human capital and financial resources, we focus on research programs and therapeutic candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic candidates or for other indications that later prove to have greater commercial potential. 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 therapeutic candidates for specific indications 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, 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 preclinical 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, 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.

We may not be successful in our efforts to expand our development portfolio of therapeutic candidates.

A key element of our strategy is to use our technology, including our novel EEV Platform and other modalities, to address intracellular targets that are drivers of diseases in genomically defined patient populations with high unmet medical need in order to build a development portfolio of therapeutic candidates. Although our research and development efforts to date have resulted in a development portfolio of potential programs and therapeutic candidates, we may not be able to continue to identify intracellular disease targets and develop therapeutic candidates. We may also pursue opportunities to acquire or in-license additional businesses, technologies or products, form strategic alliances or create joint ventures with third parties to complement or augment our existing business. However, we may not be able to identify any therapeutic candidates for our development portfolio through such acquisition or in-license.

Even if we are successful in continuing to build and expand our development portfolio, the potential therapeutic candidates that we identify may not be suitable for clinical development. For example, they may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will be successful in clinical trials or receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize therapeutic candidates, we will not be able to obtain drug revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

Where appropriate, we plan to seek approval from the FDA, EMA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval for any of our candidates, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if one or more of our therapeutic candidates receive accelerated approval from the FDA, EMA or comparable regulatory authorities, if our confirmatory trials do not verify clinical benefit, if the safety profile were to change based on post-marketing safety surveillance, or if we do not comply with rigorous post-marketing requirements, the FDA, EMA or such other regulatory authorities may seek to withdraw accelerated approval.

We plan to pursue accelerated development strategies in areas of high unmet need. We plan to seek accelerated approval pathways for our therapeutic candidates from the FDA, EMA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a therapeutic candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the therapeutic candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in

which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit, and the FDA is permitted to require, as appropriate, that such studies be underway prior to approval or within a specified period after the date of approval. Sponsors must also update the FDA on the status of these studies, and under FDORA, the FDA has increased authority to withdraw approval of a drug granted 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.

Prior to seeking accelerated approval for any of our therapeutic candidates, we will seek feedback from the FDA, EMA or comparable foreign regulatory authorities and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA or BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval, there can be no assurance that any such application will be accepted or that any approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway and subsequently converted by FDA to full approval. In addition, the FDA currently 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 any of our products. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our therapeutic candidate would result in a longer time period to commercialization of such therapeutic candidate, could increase the cost of development of such therapeutic candidate and could harm our competitive position in the marketplace. 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 a traditional approval.

We have sought and may continue to seek Fast Track designation, Breakthrough Therapy designation and/or orphan drug designation from the FDA or similar designations from other regulatory authorities for one or more of our therapeutic candidates. Even if one or more of our therapeutic candidates receive any of these designations, we may be unable to obtain or maintain the benefits associated with such designation.

The FDA has established various designations to facilitate more rapid and efficient development and approval of certain types of drugs. Such designations include Fast Track designation, Breakthrough Therapy designation, and orphan drug designation. Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions that fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the therapeutic candidate and the specific indication for which it is being studied. If any of our therapeutic candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

A Breakthrough Therapy, on the other hand, is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For therapeutic candidates 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 ineffective control regimens. Designation as a Breakthrough Therapy is within the discretion of the FDA, and drugs designated as Breakthrough Therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval. Even if one or more of our therapeutic candidates qualify as Breakthrough Therapies pursuant to FDA standards, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we may seek Breakthrough Therapy designation for one or more of our current or future therapeutic candidates, there can be no assurance that we will receive Breakthrough Therapy designation.

Regulatory authorities in some jurisdictions, including the United States and the EU, may also designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a therapeutic candidate as an orphan drug if it is a drug intended to treat a rare condition, which is generally defined as a patient

population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the European Commission may grant orphan designation to a product if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (i) such condition affects no more than five (5) in ten thousand (10,000) persons in the EU when the application is made, or (ii) it is unlikely that the product, without the benefits derived from orphan status, would generate sufficient return in the EU to justify the necessary investment in its development; and (3) there is no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or, if such a method exists, the product would be of significant benefit to those affected by that condition. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Orphan drug designation may also entitle the therapeutic to additional exclusivity in the United States. Similar benefits, including a ten year period of market exclusivity, are available to orphan products in the EU. In 2022, the FDA granted orphan drug designation to ENTR-601-44. In October 2026, the FDA granted orphan drug designation for ENTR-601-45. Even after obtaining orphan drug designation for ENTR-601-44 and ENTR-601-45, and even if we are able to obtain orphan drug designation for any other therapeutic candidate, we may not be able to obtain or maintain orphan drug exclusivity for ENTR-601-44, ENTR-601-45 or any other therapeutic candidate.

For any of our programs or therapeutic candidates that may receive Fast Track, Breakthrough Therapy or orphan drug designation by the FDA (including ENTR-601-44) or similar designations by other regulatory authorities, there is no assurance that we will receive any benefits from such programs or that we will continue to meet the criteria to maintain such designation. Even if we obtain such designations, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A Fast Track, Breakthrough Therapy, or orphan drug designation does not ensure that a therapeutic candidate will receive marketing approval or that approval will be granted within any particular timeframe.

Although we have obtained rare pediatric disease designation for ENTR-601-44, we may not be eligible to receive a priority review voucher in the event the FDA determines we no longer meet the criteria for designation, revokes the designation or FDA approval does not occur prior to September 30, 2029.

The sponsor of an application for a rare pediatric disease drug product may be eligible for a voucher that can be used or sold to obtain a priority review for a subsequent application submitted under section 505(b)(1) of the FDCA or section 351 of the PHS Act. Designation of a drug as a product for a rare pediatric disease does not guarantee that a marketing application for such drug will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Even though we have received rare pediatric disease designation for ENTR-601-44, we would need to request a rare pediatric disease priority review voucher in the marketing application for ENTR-601-44. Vouchers for rare pediatric disease drugs are awarded for qualifying applications when the drug receives approval. After September 30, 2029, the FDA may not award any rare pediatric disease priority review vouchers.

Obtaining and maintaining marketing approval or commercialization of our therapeutic candidates in the United States does not mean that we will be successful in obtaining marketing approval of our therapeutic candidates in other jurisdictions. Failure to obtain marketing approval in foreign jurisdictions would prevent any therapeutic candidates we may develop from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.

In order to market and sell any therapeutic candidates we may develop in the EU and many other foreign jurisdictions, including the UK, we or our collaborators 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, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and 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. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our medicines in any jurisdiction, which would materially impair our ability to generate revenue.

Additionally, now that the UK is no longer part of the EU, separate applications and procedures will be required to obtain regulatory approval for our products in the UK and EU. In particular, the UK is no longer covered by the centralized procedure for obtaining EU-wide marketing authorizations from the EMA for medicinal products, and a separate process for authorization of drug products will be required in the UK. However, under a new international recognition procedure which was put in place by the MHRA on January 1, 2024, the MHRA may take into account decisions on the approval of a

marketing authorization from the EMA (and certain other regulators) when considering an application for a UK marketing authorization.

In addition, the regulatory regime for medicinal products in the UK at present broadly aligns with EU regulations, however, longer term, the UK is likely to develop its own legislation that diverges from that in the EU now that its regulatory system is independent from the EU and the Trade and Cooperation Agreement entered into by the EU and UK does not provide for mutual recognition of UK and EU pharmaceutical legislation. It is possible therefore, that there will be increased regulatory complexities in the UK and EU, which could disrupt the timing of any regulatory approvals that we may determine to pursue in these jurisdictions.

The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We anticipate we will conduct clinical trials of our therapeutic candidates in the United States and internationally. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions or may not be accepted at all. In cases where data from United States clinical trials are intended to serve as the basis for marketing approval in the foreign countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of its applicable jurisdiction. For example, we are initially advancing the ENTR-601-44 and ENTR-601-45 programs in the EU and the UK, and we have not yet conducted any clinical trials for these programs in the United States. Additionally, recent policy proposals in the U.S., if enacted in the future, may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly. If the FDA does not accept data from such trials, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our therapeutic candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Changes in methods of therapeutic candidate manufacturing or formulation may result in additional costs or delay, which could adversely affect our business, results of operations and financial condition.

As therapeutic candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, we may introduce an alternative formulation of one or more of our therapeutic candidates during the course of our planned clinical trials. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our therapeutic candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our therapeutic candidates and jeopardize our ability to commercialize our therapeutic candidates, if approved, and generate revenue.

Even if we, or any collaborators we may have, obtain marketing approvals for any therapeutic candidates we may develop, the terms of approvals and ongoing regulation of our therapeutics could require the substantial expenditure of resources and may limit how we, or they, manufacture and market our therapeutics, which could materially impair our ability to generate revenue.

Any therapeutic candidate for which we obtain marketing approval, if ever, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such medicine, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current Good Manufacturing Practice ("cGMP") requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, compliance with applicable product tracking and tracing requirements, and requirements regarding the distribution of samples to physicians and recordkeeping. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The FDA typically advises that patients treated with genetic medicine undergo follow-up observations for potential adverse events for a 15-year period. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Even if marketing approval of a therapeutic candidate is granted, the approval may be subject to limitations on the indicated uses for which the medicine may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine.

Accordingly, assuming we, or any third parties we may collaborate with, receive marketing approval for one or more therapeutic candidates we may develop, we, and such collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we and such collaborators are not able to comply with post-approval regulatory requirements, we and such collaborators could have the marketing approvals for our therapeutics withdrawn by regulatory authorities and our, or such collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition and prospects.

If we fail to comply with applicable regulatory requirements following approval of any therapeutic candidates we may develop, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA, BLA or comparable foreign regulatory filing, or supplements thereto submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any therapeutic candidates we may develop and generate revenues.

Clinical trial and product liability lawsuits against us could divert our resources, could cause us to incur substantial liabilities and could limit commercialization of any therapeutic candidates we may develop.

We will face an inherent risk of clinical trial and product liability exposure related to the testing of any therapeutic candidates we may develop in clinical trials, and we will face an even greater risk if we commercially sell any products that we may develop. While we currently have no therapeutic candidates that have been approved for commercial sale, the future use of therapeutic candidates by us in our current and future clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. If we cannot successfully defend ourselves against claims that our therapeutic candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any therapeutic candidates we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- significant costs to defend any related litigation;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- decline in our stock price;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any therapeutic candidates we may develop.

We will need to increase our insurance coverage if we continue to commence clinical trials or if we commence commercialization of any therapeutic candidates. Insurance coverage is increasingly expensive. 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. If and when coverage is secured, our insurance policies may also have various exclusions and we may be subject to a product

liability claim for which we have no coverage. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

We may develop our current or future therapeutic candidates in combination with other therapies, which would expose us to additional risks.

We may develop our current or potential future therapeutic candidates in combination with one or more currently approved therapies or therapies in development. Even if any of our current or future therapeutic candidates 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, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our therapeutic candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our therapeutic candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our therapeutic candidates or our own products being removed from the market or being less successful commercially.

We may also evaluate our current or future therapeutic candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any therapeutic candidate in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

Furthermore, we cannot be certain that we will be able to obtain a steady supply of such therapies for use in developing combinations with our therapeutic candidates on commercially reasonable terms or at all. Any failure to obtain such therapies for use in clinical development and the expense of purchasing therapies in the market may delay our development timelines, increase our costs and jeopardize our ability to develop our therapeutic candidates as commercially viable therapies. If the FDA, EMA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or future therapeutic candidates, we may be unable to obtain approval of or successfully market any one or all of the current or future therapeutic candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or future therapeutic candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future therapeutic candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to Our Reliance on Third Parties

We rely, and expect to continue to rely, on third parties to conduct some or all aspects of our product manufacturing, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.

We do not expect to independently conduct all aspects of our product manufacturing, research and preclinical and clinical testing. We currently rely, and expect to continue to rely, on third parties with respect to many of these items, including contract manufacturing organizations ("CMOs") for the manufacturing of any therapeutic candidates we test in preclinical or clinical development, as well as contract research organizations ("CROs") for the conduct of our animal testing and research and CROs for the conduct of our planned clinical trials. Any of these third parties may terminate their engagements with us at any time. A need to enter into alternative arrangements could delay our product development activities, and we may not be able to enter into alternative arrangements on reasonable terms, if at all.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study protocols. For example, for therapeutic candidates that we develop and commercialize on our own, we will remain responsible for ensuring that each of our CTA/IND-enabling studies and clinical trials are conducted in accordance with the study plan and protocols. Moreover, the FDA and similar foreign regulatory bodies require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on government-sponsored databases, such as clinicaltrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory

authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure our stockholders that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under conditions that comply with cGMPs. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Although we intend to design the clinical trials for any therapeutic candidates we may develop, CROs will conduct some or all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials will also result in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- be unable to acquire the necessary supplies to perform successfully;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. 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. In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these CROs, and any other third parties we engage do not perform preclinical studies and future clinical trials in a satisfactory manner, if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, or if they breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of any therapeutic candidates we may develop may be delayed, we may not be able to obtain regulatory approval and commercialize our therapeutic candidates or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs and other third parties, we could be required to repeat, extend the duration of or increase the size of any preclinical studies or clinical trials we conduct and this could significantly delay commercialization and require greater expenditures.

Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and other regulatory authorities for therapeutic 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 other regulatory authorities may require us to suspend, place on clinical hold or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with drug product produced under cGMP requirements and may require a large number of patients. In the U.S., we also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, clinicaltrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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 therapeutic candidates. As a result, our financial results and the commercial prospects for our therapeutic candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Our failure or any failure by these third parties to comply with these 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. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

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 third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the preclinical studies and clinical trials required to support future IND/CTA submissions and approval of any therapeutic candidates we may develop.

We are dependent on third-party vendors to provide certain licenses, products and services and our business and operations, including clinical trials, could be disrupted by any problems with our significant third-party vendors.

We engage a number of third-party suppliers and service providers to supply critical goods and services, such as contract research services, contract manufacturing services and information technology services. Disruptions to the business, financial stability or operations of these suppliers and service providers, including due to strikes, labor disputes or other disruptions to the workforce, for instance, if employees are not able to come to work, or to their willingness and ability to produce or deliver such products or provide such services in a manner that satisfies the requirements put forth by the authorities, or in a manner that satisfies our own requirements, could affect our ability to develop and market our future therapeutic candidates on a timely basis. If these suppliers and service providers were unable or unwilling to continue to provide their products or services in the manner expected, or at all, we could encounter difficulty finding alternative suppliers. For example, we currently rely on foreign CROs and CMOs to manufacture our clinical materials, and may rely on foreign CROs and CMOs in the future. Foreign CMOs may be subject to U.S. legislation or investigations, sanctions, trade restrictions and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, delay or impact clinical trials, have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies and could adversely affect our financial condition and business prospects. For example, on December 18, 2025, the National Defense Authorization Act for Fiscal Year 2026 ("NDAA") was enacted, which includes Section 851, commonly referred to as the "BIOSECURE Act." The BIOSECURE Act restricts U.S. federal agencies and contractors from procuring certain biotechnology equipment or services from, or entering into contracts with, entities that use biotechnology equipment or services from designated "biotechnology companies of concern," and from expending certain federal loan or grant funds for such equipment or services. While the BIOSECURE Act is primarily directed at U.S. government procurement and funding and has not yet been fully implemented through final regulations, there remains a continued policy interest in limiting U.S. companies' relationships with biotechnology providers with relationships with foreign adversaries. The potential downstream adverse impacts on entities having only commercial relationships with any impacted biotechnology providers is unknown but may include supply chain disruptions or delays. Regional or single-source dependencies may in some cases accentuate these risks. For example, the pharmaceutical industry generally, and in some instances our Company, 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, such as those included in the NDAA. Although the U.S. Supreme Court invalidated tariffs imposed under the International Emergency Economic Powers Act in 2026, the U.S. government has since imposed tariffs under other statutory authorities, including Section 301 of the Trade Act of 1974, which are also subject to legal challenge, and has indicated that it may pursue further tariff actions. We cannot predict the results of the U.S. government's trade negotiations, the outcome of ongoing legal challenges to tariff policies or whether additional tariffs will be imposed. Even if we are able to secure appropriate alternative suppliers in a timely manner, costs for such products or services could increase significantly. Any of these events could adversely affect our results of operations and our business.

Our EEV-based therapeutic candidates are based on novel technologies and any therapeutic candidates we develop may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life,

testing, storage, supply chain management or shipping. If we or any of our third-party manufacturers encounter such difficulties, our ability to supply material for clinical trials or any approved product could be delayed or stopped.

The manufacturing processes for our therapeutic candidates are novel. There are no medicines incorporating or utilizing our EEV Platform that have been commercialized to date. Due to the novel nature of this technology and limited experience at larger scale production, we may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management, or shipping. These difficulties could be due to any number of reasons including, but not limited to, complexities of producing batches at larger scale, equipment failure, choice and quality of raw materials and excipients, analytical testing technology, and product instability. In an effort to optimize product features, we have in the past and may in the future make changes to our therapeutic candidates in their manufacturing and stability formulation and conditions. This has in the past resulted in and may in the future result in our having to resupply batches for preclinical or clinical activities when there is insufficient product stability during storage and insufficient supply. Insufficient stability or shelf life of our therapeutic candidates could materially delay our or our strategic collaborators' ability to continue the clinical trial for that therapeutic candidate or require us to begin a new clinical trial with a newly formulated drug product, due to the need to manufacture additional preclinical or clinical supply.

Our rate of innovation is high, which has resulted in and will continue to cause a high degree of technology change that can negatively impact product comparability during and after clinical development. Furthermore, technology changes may drive the need for changes in, modification to, or the sourcing of new manufacturing infrastructure or may adversely affect third-party relationships.

The process to generate our EEV-based therapeutics is complex and, if not developed and manufactured under well-controlled conditions, can adversely impact pharmacological activity. Furthermore, we have not manufactured our EEV-based therapeutics at commercial scale. We may encounter difficulties in scaling up our manufacturing process, thereby potentially impacting clinical and commercial supply.

During clinical development of our EEV-based therapeutics, in many cases, we may have to utilize multiple batches of drug substance and drug product to meet the clinical supply requirement of a single clinical trial. Failure in our ability to scale up batch size or failure in any batch may lead to a substantial delay in our clinical trials.

As we continue developing new manufacturing processes for our drug substance and drug product, the changes we implement to manufacturing process may in turn impact specification and stability of the drug product. Changes in our manufacturing processes may lead to failure of lots and this could lead to a substantial delay in our clinical trials. Our EEV-based therapeutic candidates may prove to have a stability profile that leads to a lower than desired shelf life of our final approved EEV-based product. This poses risk in supply requirements, wasted stock, and higher cost of goods.

Due to the number of different programs, we may have cross contamination of products inside of our factories, CROs, suppliers, or in the clinic that affect the integrity of our therapeutics.

As we scale the manufacturing output for particular programs, we plan to continuously improve yield, purity, and the pharmaceutical properties of our development candidates from IND-enabling studies through commercial launch, including shelf life stability, and solubility properties of drug product and drug substance. Because of continuous improvement in manufacturing processes, we may switch processes for a particular program during development. However, after the change in process, more time is required for pharmaceutical property testing, such as 6 or 12 month stability testing. That may require resupplying clinical material, or making additional cGMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed.

We are utilizing a number of raw materials and excipients that are either new to the pharmaceutical industry or are being employed in a novel manner. Some of these raw materials and excipients have not been scaled to a level to support commercial supply and could experience unexpected manufacturing or testing failures, or supply shortages. Such issues with raw materials and excipients could cause delays or interruptions to clinical and commercial supply of our therapeutic candidates. Further, now and in the future one or more of our programs may have a single source of supply for raw materials and excipients.

We may establish a number of analytical assays to assess the quality of our EEV-based therapeutic candidates. We may identify gaps in our analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, we may discover new impurities that have an impact on product safety, efficacy, or stability. This may lead to an inability to release our therapeutic candidates until the manufacturing or testing process is rectified.

We may find that our therapeutic candidates are extremely temperature sensitive, and we may learn that any or all of our therapeutics are less stable than desired. We may also find that transportation conditions negatively impact product

quality. This may require changes to the formulation or manufacturing process for one or more of our therapeutic candidates and result in delays or interruptions to clinical or commercial supply. In addition, the cost associated with such transportation services and the limited pool of vendors may also add additional risks of supply disruptions.

We may from time to time be dependent on single- or limited-source suppliers for some of the components and materials used in the therapeutic candidates we may develop.

We may from time to time depend on single- or limited-source suppliers for some of the components and materials used in any therapeutic candidates we may develop. We cannot ensure that these suppliers or service providers will remain in business, have sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of raw materials, components, key processes and finished goods could expose us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or service provider could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

If we have to switch to a replacement supplier, the manufacture and delivery of any therapeutic candidates we may develop could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers, if required, may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single source components and materials used in our therapeutics, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our investigational medicines.

We have and may in the future enter into collaborations, licenses and other similar arrangements with third parties for the research, development and commercialization of certain of the therapeutic candidates we may develop, including our collaboration with Vertex. If any such arrangements are not successful, we may not be able to capitalize on the market potential of those therapeutic candidates.

We may seek third-party collaborators for the research, development and commercialization of certain of the therapeutic candidates we may develop. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our partners dedicate to the development or commercialization of any therapeutic candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any arrangement that we enter into.

Collaborations involving our research programs or any therapeutic candidates we may develop pose numerous risks to us, including the following:

- collaborators would have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any therapeutic candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay programs, preclinical studies or clinical trials, provide insufficient funding for programs, preclinical studies or clinical trials, stop a preclinical study or clinical trial or abandon a therapeutic candidate, repeat or conduct new clinical trials or require a new formulation of a therapeutic candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with any therapeutic candidates we may develop if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- collaborators may be acquired by a third party having competitive products or different priorities, causing the emphasis on our product development or commercialization program under such collaboration to be delayed, diminished or terminated;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- if a collaborator of ours is involved in a business combination, the collaborator might de-emphasize or terminate the development or commercialization of any therapeutic candidate licensed to it by us;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of any therapeutic candidates we may develop or that result in costly litigation or arbitration that diverts management attention and resources;
- we may lose certain valuable rights under certain circumstances, including if we undergo a change of control;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable therapeutic candidates we may develop;
- our collaborators' business or operations could be disrupted due to reasons outside of our control, such as global health crises, macroeconomic conditions and geopolitical developments, evolving regulatory activities and policy changes under the current U.S. government, changes to rates of inflation and interest rates and uncertainty about economic and global stability, which could have an adverse impact on their development and commercialization efforts or the prospects of our collaboration; and
- collaboration agreements may not lead to development or commercialization of therapeutic candidates in the most efficient manner or at all.

If our collaborations do not result in the successful development and commercialization of therapeutic candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of therapeutic candidates could be delayed, and we may need additional resources to develop therapeutic candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report apply to the activities of our collaborators.

For example, we will have limited influence and control over the development and commercialization activities of Vertex in the development and commercialization of VX-670 or certain other product candidates. Vertex has announced that it expects to share the interim results of the GALILEO global Phase 1/2 clinical study of VX-670 in people with DM1 in the second half of 2026.Vertex's development and commercialization activities may adversely impact our own efforts. Failure by Vertex to meet its obligations under the Vertex Agreement, to apply sufficient efforts at developing and commercializing collaboration products, or to comply with applicable legal or regulatory requirements, may materially adversely affect our business and our results of operations. In addition, to the extent we rely on Vertex to commercialize any products upon obtaining regulatory approval, we may receive less revenue than if we commercialized these products ourselves, which could materially harm our prospects.

These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach definitive collaboration agreements 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 several factors. If we license rights to any therapeutic candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

If conflicts arise between us and our current or potential collaborators, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between us and our current or potential collaborators, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Our collaborators may develop, either alone or with others,

products in related fields that are competitive with the therapeutic candidates we may develop that are the subject of these collaborations with us. Competing products, either developed by the collaborators or to which the collaborators have rights, may result in the withdrawal of support for our therapeutic candidates.

Some of our future collaborators could also become our competitors. Our collaborators could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, fail to devote sufficient resources to the development and commercialization of products, or merge with or be acquired by a third party who may do any of these things. Any of these developments could harm our product development efforts.

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

Our product development and research programs and the potential commercialization of any therapeutic candidates we may develop will require substantial additional cash to fund expenses. For some of the therapeutic candidates we may develop, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those therapeutic 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, the EMA or similar regulatory authorities outside the United States, the potential market for the subject therapeutic candidate, the costs and complexities of manufacturing and delivering such therapeutic candidate to patients, the potential of competing products, 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 collaborator may also consider alternative therapeutic 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.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent 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 therapeutic 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, reduce the scope of any sales or marketing activities, or increase our own expenditures on the development of the therapeutic candidate.

Risks Related to Commercialization of Our Therapeutic Candidates

The commercial success of our therapeutic candidates will depend upon the degree of market acceptance of such therapeutic candidates by physicians, patients, healthcare payors and others in the medical community.

Our therapeutic candidates may not be commercially successful. Even if any of our therapeutic candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. The commercial success of any of our current or future therapeutic candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. The degree of market acceptance of our therapeutics will depend on a number of factors, including:

- the demonstration of clinical efficacy and safety compared to other more-established products;
- the indications for which our therapeutic candidates are approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- the acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our therapeutics, as well as the cost of treatment with our therapeutics in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;

- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our therapeutics in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our therapeutics, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our therapeutics as well as competitive drugs;
- the effectiveness of our or any of our current or potential future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product.

If any therapeutic candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our therapeutics may require significant resources and may never be successful.

Even if we are able to commercialize any of our therapeutic candidates, if approved, such therapeutic candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing 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 therapeutic candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the therapeutic candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the therapeutic candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more therapeutic candidates, even if our therapeutic candidates obtain marketing approval. For more information, please see the section titled "*Business — Government Regulation — Coverage, Pricing and Reimbursement*" included in our Annual Report.

Our ability to commercialize any therapeutic candidates successfully also will depend in part on the extent to which coverage and reimbursement for these therapeutic candidates and related treatments will be available from government authorities, private health insurers and other organizations. In the U.S. and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments. Sales of these or other products that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our therapeutics will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our therapeutics. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Factors payors consider in determining reimbursement are based on whether the 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.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts

from list prices and are challenging the prices charged for products. We cannot be sure that coverage will be available for any therapeutic candidate that we commercialize and, if coverage is available, the level of reimbursement.

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 therapeutic 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 ("ASP") 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.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular therapeutic candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our therapeutic candidates. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower.

We face significant competition, and if our competitors develop technologies or therapeutic candidates more rapidly than we do or their technologies are more effective, our business and our ability to develop and successfully commercialize products may be adversely affected.

The biotechnology and biopharmaceutical industries are characterized by rapid advancing technologies, intense competition and a strong emphasis on proprietary and novel products and therapeutic candidates. Our competitors have developed, are developing or may develop products, therapeutic candidates and processes competitive with our therapeutic candidates. Any therapeutic candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop therapeutic candidates. Our competitors include larger and better funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions who may be active in the indications we are targeting and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new therapeutic candidates. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Currently, patients with DMD are treated with corticosteroids to manage the inflammatory component of the disease. EMFLAZA (deflazacort) is an FDA-approved corticosteroid marketed by PTC Therapeutics, Inc. ("PTC") and AGAMREE (vamorolone) is a novel alternative steroid marketed by Catalyst Pharmaceuticals. Duvyzat (givinostat) is an oral medication marketed by ITF Therapeutics for patients six years of age and older. Duvyzat is a histone deacetylase (HDAC) inhibitor that works by targeting pathogenic processes to reduce inflammation and loss of muscle. There are four FDA-approved (accelerated approval) exon skipping drugs: EXONDYS 51 (eteplirsen), VYONDYS 53 (golodirsen), and AMONDYS 45 (casimersen), which are PMOs approved for the treatment of patients with DMD who are amenable to exon 51, exon 53 and exon 45 skipping, respectively, and are marketed by Sarepta Therapeutics, Inc. ("Sarepta"), and VILTEPSO (viltolarsen), a PMO approved for the treatment of patients with DMD who are amenable to exon 53 skipping, which is marketed by Nippon Shinyaku Co. Ltd ("Nippon"). Sarepta submitted sNDAs in April 2026 seeking conversion of AMONDYS 45 and VYONDYS 53 to full approval (PDUFA of February 28, 2027). Sarepta also markets Elevidys (delandistrogene moxeparvovec-rokl), a gene therapy for the treatment of DMD for ambulatory individuals 4 years of age and older.

Companies focused on developing treatments for DMD that target dystrophin production mechanisms, as does our DMD program, include Nippon, which is in a Phase 2 clinical trial with brogidirsen for patients amenable to exon 44 skipping and with NS-050 in Phase 1/2 clinical trial for patients amenable to exon 50 skipping and NS-051 in pre-clinical stage, PTC with ataluren, a small molecule targeting nonsense mutations which is marketed outside the United States (PTC

withdrew the Translarna NDA resubmission in Feb 2026 after FDA feedback), Avidity Biosciences, Inc. ("Avidity"), which is a fully owned subsidiary of Novartis, which filed a BLA seeking accelerated approval for del-zota, an antibody oligonucleotide conjugate for exon 44 (accepted for priority review) in June of 2026 (Novartis is currently running both a managed access program in the United States and a Phase 3 trial ex-US), and has similar programs in preclinical development for patients amenable to exon 45 skipping, which they expect to enter the clinic in 2027, and exon 51 skipping, Wave Life Sciences Ltd., which is clinically evaluating WVE-N531, a splicing clinical candidate that is designed to target exon 53 within the dystrophin gene, Dyne Therapeutics, Inc. ("Dyne"), which is pursuing antibody fragment-oligonucleotide conjugates for exons 44, 45, 51 and 53 (the clinical candidate z-rostudirsen formerly known as DYNE-251 - BLA filed in May 2026 and accepted with Priority Review with a PDUFA of January 21, 2027), BioMarin Pharmaceutical Inc., which is in clinical development with BMN 351 (nivudirsen), an antisense oligonucleotide therapy for exon 51 currently in Phase 1/2, and SQY Therapeutics with SQY 51, an antisense oligonucleotide therapy being evaluated in a Phase 1/2 trial in France (granted Orphan Drug Designation in US). In addition, several companies are developing gene therapies to treat DMD, including Solid Biosciences Inc. (SGT-003), and REGENXBIO (RGX-202). We are also aware of several companies targeting gene editing, such as Precision Biosciences (enrolling a Phase 1/2a open-label trial for ambulatory boys with confirmed mutations within exons 45 through 55 - first participant dosed in August 2026), and non-dystrophin mechanisms for the treatment of DMD, such as Satellos Bioscience Inc., a company developing a small molecule AAK1 inhibitor (Forazapadin) promoting asymmetric muscle stem cell division (in Phase 2 clinical trials) and Capricor Therapeutics has deramiocel (allogeneic cardiosphere-derived cells) in a BLA under review, with a PDUFA date extended to November 22, 2026.

We expect to face competition alongside our partner from existing products and products in development for each of our therapeutic candidates. There are currently no approved therapies to treat the underlying cause of DM1. Therapeutic candidates currently in development to treat DM1 include: tideglusib, a GSK3-ß inhibitor in late-stage clinical development by AMO Pharma Ltd. for the congenital phenotype of DM1; "Del-desiran", an antibody linked siRNA in clinical development by Avidity/Novartis which recently failed to meet its primary endpoint (vHOT) in a Phase 3 clinical trial; Zeleciment Basivarsen, an antibody fragment conjugated to an ASO targeting DM1 protein kinase knockdown in clinical development by Dyne with registrational expansion cohort data expected in the first quarter of 2027; PGN-EDODM1, a linear peptide conjugated to a PMO targeting CUG repeats in clinical development by PepGen, Inc. with 10 mg/kg data expected in the fourth quarter of 2026; an αvβ6 integrin-targeted siRNA conjugate, SRP-1003, targeting DMPK knockdown, which is in development by Sarepta, licensed from Arrowhead Pharmaceuticals, with recently announced preliminary data from its Phase 1/2 clinical trial; a small molecule DT-818 targeting GTG repeats development by Design Therapeutics, Inc. which initiated a Phase 1 MAD trial in 2026; ATX-01 (anti-miR-23b), a clinical-stage DM1 program from ARTHEx in Phase 1/2a; and small molecules interacting with RNA in preclinical development by Expansion Therapeutics, Inc.

We also expect to face competition from several products in clinical and preclinical development for Usher syndrome. The most advanced is ultevursen, which is an exon 13 skipping antisense oligonucleotide therapy in Phase 2b development from Sepul Bio., a business unit of Laboratoires Théa (Phase 2b LUNA enrollment completed July 2026). Nacuity Pharmaceuticals, Inc. has completed a Phase 1/2 clinical trial with NPI-001, which is a small molecule which targets oxidative stress. Reforgene is developing RM-101, a subretinal injection mini-gene AAV-snRNA targeting exon 13 skipping, and has completed an investigator-initiated trial in China and received IND clearance in the US and China. There are also ASO, mini-gene, and other gene editing approaches reported in discovery from several companies.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any therapeutic candidate, we will face competition based on many different factors, including the safety and effectiveness of our therapeutics, the ease with which our therapeutics can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products or technological approaches may make any products we develop, or our EEV Platform, obsolete or noncompetitive before we recover the expense of developing and commercializing our therapeutic candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our therapeutics we may develop, if approved, could be adversely affected.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain key employees and to attract, retain and motivate qualified personnel.

We are highly dependent on the research expertise of Natarajan Sethuraman, Ph.D., our President of Research and Development, and the development and management expertise of Dipal Doshi, our Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements and/or offer letters with our executive officers, each of them may terminate their employment with us at any time.

Our industry has experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, clinical, regulatory, manufacturing and management skills and experience. We conduct our operations in the Boston area, a region that is home to many other pharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among pharmaceutical companies. Many of the other pharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our therapeutic candidates and to grow our business and operations as currently contemplated.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. For example, employment of our key employees is at-will, which means that any of our employees could leave our employment at any time, with or without notice.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our therapeutic candidates and decrease the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our therapeutic candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any therapeutic candidates for which we obtain marketing approval.

For example, the Patient Protection and Affordable Care Act ("ACA") was passed in 2010 and substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. In addition, U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes.

Among the provisions of the ACA of importance to our potential therapeutic candidates are the following:

- annual fees and taxes on manufacturers of certain branded prescription drugs;
- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations;

- expansion of healthcare fraud and abuse laws, including the False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report financial arrangements with physicians and teaching hospitals;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. Subsequent legislation extended the 2% payment reduction which remains in effect through fiscal year 2031, absent additional action from Congress. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap, set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. The One Big Beautiful Bill Act of 2025 (the "OBBBA") also added work requirements and more frequent eligibility enrollment reverifications for Medicaid enrollees, which is expected to have the effect of reducing the number of Medicaid enrollees. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

The Inflation Reduction Act of 2022 (the "IRA") includes several provisions that may impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, 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 the rebate rule that would limit the fees that pharmacy benefit managers can charge. Previously, under the IRA, orphan drugs were exempted from the Medicare drug price negotiation program, only if they have 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. The OBBBA eliminated this restriction, which serves to exempt all orphan drugs from the Medicare drug price negotiation program, regardless of the number of orphan designations or indications. 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.

Further, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. 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." 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. The Administration has also entered into voluntary most-favored-nation ("MFN")

pricing agreements with over 20 major manufacturers, including commitments relating to Medicaid pricing, new product launches and participation in TrumpRx.gov. 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.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs. The first proposal, the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") for Medicare Part B, was finalized in September 2026 and will require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The final rule excludes certain categories of products and manufacturers, including certain orphan drugs and cell and gene therapies. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. The GLOBE Model is scheduled to begin in 2027 and may be subject to legal challenges, while GUARD has not yet been finalized. These models, if applicable to products developed by our collaborators, could adversely affect the milestone payments and royalties we may receive under our collaboration arrangements. Additionally, in November 2025, CMS introduced the GENErating cost Reductions for U.S. Medicaid ("GENEROUS") Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

In addition, at the state level, legislatures have increasingly passed legislation and implemented regulations similar to those under consideration at the federal level, as well as laws designed to control pharmaceutical and biotherapeutic product pricing, including price or patient reimbursement constraints at the state government level, limitations on discounts to patients, restrictions or other limitations on patient assistance and certain product access and marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards and similar entities. While many PDABs have been granted authority to promote drug price transparency and reporting, some states have granted PDABs more expansive authority, including to set Upper Payment Limits ("UPLs") on select, high price drugs. The adoption and implementation of UPLs may put downward pressure on drug prices and impact our company's future revenues.

We expect that the ACA, as well as other healthcare reform measures that 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. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our therapeutics. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. 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. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our therapeutic candidates, if any, may be. It is also possible that additional governmental action is taken in response to pandemics or global health crises. For more information, please see the section titled "*Business — Government Regulation — Healthcare Reform*" included in our Annual Report.

Cybersecurity incidents, data breaches, loss or leakage of data and other disruptions or failures of our internal information technology systems, or those of our third-party CROs or other vendors, contractors or consultants could result in the disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced

elements of our operations to third parties, and as a result we manage a number of third-party CROs, vendors, and other contractors and consultants who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs, vendors and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as data breaches or cybersecurity incidents from inadvertent or intentional actions by our employees, third-party CROs, vendors, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering (including phishing attacks) and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure, or that of our third-party CROs, vendors and other contractors and consultants, or lead to data leakage. Furthermore, the use of artificial intelligence ("AI") technologies by use and third-party vendors can also give rise to cybersecurity risks as well as intellectual property risks, including the disclosure or compromise of our confidential information or other proprietary intellectual property through the use of generative AI tools, or the ability to assert or defend ownership rights in intellectual property created with the use of generative AI tools. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business. The risk of a cybersecurity incident, data breach, or other disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. Attempts to disrupt or gain unauthorized access to our and our third-party vendors' information systems from malicious third parties or insider threats may incorporate widely varying and frequently changing tactics. The techniques used by cyber criminals change frequently and may be enhanced or facilitated by evolving technologies such as AI. Cyber attacks may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. To the extent that any disruption, data breach, or cybersecurity incident were to result in a loss of, or damage to, our data or applications, or those of our third-party CROs, vendors and other contractors and consultants, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of ENTR-601-44, ENTR-601-45, ENTR-601-50, ENTR-601-51, ENTR-801, our partnered candidate VX-670 or any future therapeutic candidates could be delayed. The costs related to significant cybersecurity incidents, data breaches, or other disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks. If the information technology systems of our third-party CROs, vendors and other contractors and consultants become subject to disruptions, data breaches, or cybersecurity incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Further, 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 will be sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations.

Like other companies in our industry, we, and our third party vendors, have experienced threats and cybersecurity incidents relating to our information technology systems and infrastructure. Significant breakdowns, data leakages, data breaches, cybersecurity incidents in our systems, or those of our third-party CROs, vendors and other contractors and consultants, or other disruptions may have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, or those of our third-party CROs, vendors and other contractors and consultants, it could result in a material disruption of our programs and the development of our therapeutic candidates could be delayed. In addition, the loss of clinical trial data for ENTR-601-44, ENTR-601-45, ENTR-601-50, ENTR-601-51, ENTR-801, our partnered candidate VX-670 or any other therapeutic candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or those of our third-party CROs, vendors and other contractors and consultants, data breaches, or cybersecurity incidents could result in the loss, misappropriation and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state cybersecurity incident notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

A pandemic, epidemic or outbreak of an infectious disease may materially and adversely affect our business and could cause a disruption to the development of our therapeutic candidates.

Public health crises could adversely impact the global economy and financial markets, and put a significant strain on healthcare resources. Worldwide pandemics may affect our ability to initiate and complete preclinical studies, delay the initiation of our planned clinical trials, disrupt regulatory activities or have other adverse effects on our business, results of operations, financial condition and prospects.

Failure to comply with environmental, health and safety laws and regulations could subject us to fines or penalties or incur costs that could harm our business.

We are subject to numerous foreign, federal, state and local environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources, including any available insurance.

In addition, our leasing and operation of real property may subject us to liability pursuant to certain of these laws or regulations. Under existing U.S. environmental laws and regulations, current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures, or injunctions limiting or altering our operations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations, which are becoming increasingly more stringent, may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any therapeutic candidates for which we obtain regulatory approval. Our current and future arrangements with 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 conduct research and would market, sell and distribute our therapeutics. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. 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 or federal civil money penalties;

- the federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of 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"), which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services 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 respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to 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;
- the U.S. federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program 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), certain other licensed health care practitioners (defined to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified-nurse midwives) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. 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 on May 25, 2018) ("EU GDPR") and the UK General Data Protection Regulation (which became effective following UK withdrawal from the EU as of January 2021) ("UK GDPR") 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. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource consuming and can divert a company's attention from the business.

Ensuring that our internal operations and future 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 do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected. For more information, please see the section titled "*Business — Government Regulation — Healthcare Law and Regulation"* included in our Annual Report.

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

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, 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 governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are subject to certain U.S. and certain foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations prohibit, among other things, companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies and clinical trials and/or to obtain necessary permits, licenses, patent registrations and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior 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.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Legislation or other changes in U.S. tax law 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. For example, the OBBBA was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Changes to tax laws (certain of 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, or the Code, 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. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

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 enacted, 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. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

Our ability to use our U.S. net operating loss carryforwards and certain other U.S. tax attributes may be limited.

Our ability to use our U.S. federal and state net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses.

Under current law, unused U.S. federal net operating losses generated for tax years beginning after December 31, 2017 are not subject to expiration and may be carried forward indefinitely. Such U.S. federal net operating losses generally may not be carried back to prior taxable years, except that, net operating losses generated in 2018, 2019 and 2020 may be carried back to each of the five tax years preceding the tax years of such losses. Additionally, for taxable years beginning after December 31, 2020, the deductibility of such U.S. federal net operating losses is limited to 80% of our taxable income in any future taxable year. In addition, both our current and our future unused U.S. federal net operating losses and tax credits may be subject to limitation under Sections 382 and 383 of the Code, if we undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period. We have determined that such ownership changes have occurred in the past, and we may experience additional ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Our net operating losses and tax credits may also be impaired or restricted under state law. As of December 31, 2025, we had U.S. federal net operating loss carryforwards of approximately $178.3 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us.

We plan to distribute our technology, biology, execution and financing risks across a wide variety of therapeutic areas, disease states, programs, and technologies. However, our assessment of, and approach to, risk may not be comprehensive or effectively avoid delays or failures in one or more of our programs or modalities. Failures in one or more of our programs or modalities could adversely impact other programs or modalities in our development portfolio and have a material adverse impact on our business, results of operations and ability to fund our business.

We are creating a new category of potential therapeutics, using our proprietary technology, including EEV peptides and other modalities, to improve the lives of patients. We have designed our strategy and operations to realize the full potential value and impact of our technology over a long time horizon across a broad array of human diseases. We have made investments in our platform, infrastructure, and clinical capabilities that have enabled us to establish a development portfolio of several programs in development. As our therapeutic candidates and discovery programs progress, we or others may determine: that certain of our risk allocation decisions were incorrect or insufficient; that we made platform level technology mistakes; that individual programs or our science in general has technology or biology risks that were unknown or underappreciated; that our choices on how to develop our infrastructure to support our scale will result in an inability to manufacture our therapeutics for clinical trials or otherwise impair our manufacturing; or that we have allocated resources in such a way that large investments are not recovered and capital allocation is not subject to rapid re-direction. All of these risks may relate to our current and future programs sharing similar science (including EEV science) and infrastructure, and in the event material decisions in any of these areas turn out to have been incorrect or under-optimized, we may experience a material adverse impact on our business and ability to fund our operations and we may never realize what we believe is the potential of our technology.

While we will attempt to diversify our risks by developing one or more programs in each modality, there are risks that are unique to each modality and risks that are applicable across modalities. These risks may impair our ability to advance one or more of our programs in clinical development, obtain regulatory approval, or ultimately commercialize our programs, or cause us to experience significant delays in doing so, any of which may materially harm our business.

Certain features in our therapeutic candidates, including those related to proteins and oligonucleotides, and their components, may result in foreseen and unforeseen risks that are active across some or all of our modalities. In addition, the biology risk across much of our development portfolio represents targets and pathways not clinically validated by one or more approved drugs. While we believe we have made progress in seeking to reduce biology risk in certain settings, the risk that the targets or pathways that we have selected may not be effective could continue to apply across our current and future programs. Any such portfolio spanning risks, whether known or unknown, if realized in any one of our programs would have a material and adverse effect on our other programs and on our business as a whole.

Successful development of intracellular therapeutics is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Intracellular therapeutics that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- nonclinical or preclinical testing or study results may show our therapeutics to be less effective than desired or to have harmful or problematic side effects or toxicities;
- clinical trial results may show our oligonucleotides to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical trials, patients dropping out of trials, length of time to achieve trial endpoints, additional time requirements for data analysis, NDA or BLA preparation, discussions with the FDA, a failure to align with the FDA regarding clinical trial endpoints and related approval criteria, an FDA request for additional nonclinical or clinical data, or unexpected safety or manufacturing issues;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make our therapeutics uneconomical; and
- proprietary rights of others and their competing products and technologies that may prevent our therapeutics from being commercialized.

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 the Company's current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems.

Although we assess our banking and customer 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 affect the Company, the financial institutions with which the Company has 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. These factors could involve financial institutions or financial services industry companies with which the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Potential or actual breach of statutory, regulatory or contractual obligations, including obligations that require the Company to maintain letters of credit or other credit support arrangements; and
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity, our current and/or planned business operations, and our current or projected financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our suppliers, which in turn, could have a material adverse effect on our current and/or planned

business operations and our current or projected results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on the Company, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer, collaborator or supplier bankruptcy or insolvency, or the failure of any customer or collaborator to make payments when due, or any breach or default by a customer, collaborator or supplier, or the loss of any significant supplier or collaborator relationships, could result in material losses to the Company and may have a material adverse impact on our business.

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.

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. 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.

Risks Related to Our Intellectual Property

If we or our collaborators are unable to obtain and maintain patent protection for our therapeutic programs and other proprietary technologies we develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our therapeutic programs and other proprietary technologies we may develop may be adversely affected.

Our success depends in large part on our ability and the abilities of our collaborators to obtain and maintain patent protection in the United States and other countries with respect to our therapeutic programs and other proprietary technologies we may develop. In order to protect our proprietary position, we have filed or intend to file patent applications in the United States and abroad relating to our therapeutic programs and other proprietary technologies we may develop; however, there can be no assurance that any such patent applications will issue as granted patents. If we are unable to obtain or maintain patent protection with respect to our therapeutic programs and other proprietary technologies we may develop, our business, financial condition, results of operations and prospects could be materially harmed.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. In addition, we may rely on third-party collaborators or licensors to file patent applications relating to therapeutic programs or proprietary technology that may be developed or in-licensed. We cannot predict whether the patent applications we are currently pursuing, or that we or our third-party collaborators or licensors may pursue, will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection against competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, 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. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

No consistent policy regarding the scope of claims allowable in patents in the biotechnology field has emerged in the United States, and the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our patent applications may not result in patents being issued which protect our therapeutic programs and other proprietary technologies we may develop or which effectively prevent others from commercializing competitive technologies and products. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We do not currently have issued patents that cover all of our technology or therapeutic candidates. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future. Moreover, even issued patents do not provide us with the right to practice our technology in relation to the commercialization of our therapeutics. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our patented therapeutic candidates and practicing our proprietary technology. Our issued patents, those that may issue in the future and those that we in-license may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or limit the length of the term of patent protection that we may have for our therapeutic candidates. Furthermore, our competitors may independently develop similar technologies.

Moreover, the claim coverage in a patent application can be significantly reduced before the patent is granted. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents issuing from our patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our therapeutic programs and other proprietary technology will be protectable or remain protected by valid and enforceable patents. For example, we do not currently have any issued patents covering any of our oligonucleotide therapeutic candidates. The extent to which any patents, if and when granted, will cover our therapeutic candidates is uncertain. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. In addition, given the amount of time required for the development, testing and regulatory review of our therapeutic programs and eventual therapeutic candidates, patents protecting the therapeutic candidates might expire before or shortly after such therapeutic candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office ("USPTO") or in other jurisdictions, or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our therapeutic programs and other proprietary technologies we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future therapeutic candidates.

Our rights to develop and commercialize any therapeutic candidates are subject and may in the future be subject, in part, to the terms and conditions of licenses granted to us by third parties. If we fail to comply with our obligations under our current or future intellectual property license agreements or otherwise experience disruptions to our business relationships with our current or any future licensors, we could lose intellectual property rights that are important to our business.

We are and expect to continue to be reliant upon third-party licensors for certain patent and other intellectual property rights that are important or necessary to the development of our therapeutic programs, eventual therapeutic candidates, and proprietary technologies. For example, we currently have a license from OSIF, an affiliate of The Ohio State University ("OSU") to certain patent rights and know-how of OSU. Our license agreement with OSIF imposes, and we expect that any future license agreement will impose, specified diligence, milestone payments, royalty payments, commercialization, development and other obligations on us and require us to meet development timelines, or to exercise

diligent or commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. These milestone payments, and other payments associated with the license, will make it less profitable for us to develop and potentially commercialize our therapeutic candidate. If this agreement is terminated, we could lose intellectual property rights that may be important to our business, potentially be liable for damages to the licensor or potentially be prevented from developing and commercializing our therapeutic candidate. Termination of the agreement or reduction or elimination of our rights under the agreement may also potentially result in us being required to negotiate a new or reinstated agreement with less favorable terms, and it is possible that we may be unable to obtain any such additional license at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to spend time and resources to redesign our therapeutic candidate or the method for manufacturing it or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. For more information on the terms of the license agreement with OSIF, please see the section titled "*Business — Intellectual property — License Agreement with The Ohio State University*" and "*Note 10, Commitments and Contingencies*" to our consolidated financial statements included in our Annual Report.

Furthermore, our licensors have, or may in the future have, the right to terminate a license if we materially breach the agreement and fail to cure such breach within a specified period or in the event we undergo certain bankruptcy events. In spite of our best efforts, our current or any future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements. If our license agreements are terminated, we may lose our rights to develop and commercialize therapeutic candidates and technology, lose patent protection, experience significant delays in the development and commercialization of our therapeutic candidates and technology, and incur liability for damages. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, our competitors or other third parties could have the freedom to seek regulatory approval of, and to market, products and technologies identical or competitive to ours and we may be required to cease our development and commercialization of certain of our therapeutic candidates and technology. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with any therapeutic candidates we may develop and our technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted and obligations imposed under the license agreement and other interpretation-related issues;
- our or our licensors' ability to obtain, maintain and defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, therapeutic candidates and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other intellectual property rights under our license agreements;
- our diligence, development, regulatory, commercialization, financial or other obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, any current or future license agreements to which we are a party, including our license agreement with OSIF, are likely to be, complex, and certain provisions in such agreements 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 technology, or increase what we believe to be our diligence, development, regulatory, commercialization, financial or other obligations under the relevant agreement. In addition, if disputes over intellectual property that we have licensed or any other dispute related to our license agreements prevent or impair our ability to maintain our current license agreements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected therapeutic candidates and technology. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

License agreements we may enter into in the future may be non-exclusive. Accordingly, third parties may also obtain non-exclusive licenses from such licensors with respect to the intellectual property licensed to us under such license agreements. Accordingly, these license agreements may not provide us with exclusive rights to use such licensed patent and other intellectual property rights, or may not provide us with exclusive rights to use such patent and other intellectual

property rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and any therapeutic candidates we may develop in the future.

Moreover, some of our in-licensed patent and other intellectual property rights may in the future be subject to third party interests such as co-ownership. If we are unable to obtain an exclusive license to such third-party co-owners' interest, in such patent and other intellectual property rights, such third-party co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We or our licensors may need the cooperation of any such co-owners of our licensed patent and other intellectual property rights in order to enforce them against third parties, and such cooperation may not be provided to us or our licensors.

Additionally, we may not have complete control over the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. It is possible that our licensors' filing, prosecution and maintenance of the licensed patents and patent applications, enforcement of patents against infringers or defense of such patents against challenges of validity or claims of enforceability may be less vigorous than if we had conducted them ourselves, and accordingly, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to file, prosecute, maintain, enforce and defend such patents and patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our technology and any therapeutic candidates we may develop that are the subject of such licensed rights could be adversely affected and we may not be able to prevent competitors or other third parties from making, using and selling competing products.

Furthermore, our owned and in-licensed patent rights may be subject to a reservation of rights by one or more third parties, including the U.S. government. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. When new technologies are developed with government funding, in order to secure ownership of patent rights related to the technologies, the recipient of such funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. A failure to meet these obligations may lead to a loss of rights or the unenforceability of relevant patents or patent applications. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as march-in rights). If the U.S. government exercised its march-in rights in our current or future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. If the U.S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The U.S. government's rights may also permit it to disclose the funded inventions and technology, which may include our confidential information, to third parties and to exercise march-in rights to use or allow third parties to use the technology that was developed using U.S. government funding. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Any of the foregoing could harm our business, financial condition, results of operations and prospects significantly.

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

Filing, prosecuting, maintaining, enforcing and defending patents and other intellectual property rights on our technology and any therapeutic candidates we may develop in all jurisdictions throughout the world would be prohibitively expensive, and accordingly, our intellectual property rights in some jurisdictions outside the United States could be less extensive than those in the United States. In some cases, we or our licensors may not be able to obtain patent or other intellectual property protection for certain technology and therapeutic candidates outside the United States. In addition, the laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors may not be able to obtain issued patents or other intellectual property rights covering any therapeutic candidates we may develop and our technology in all jurisdictions outside the United States

and, as a result, may not be able to prevent third parties from practicing our and our licensors' inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Third parties may use our technologies in jurisdictions where we and our licensors have not pursued and obtained patent or other intellectual property protection to develop their own products and, further, may export otherwise infringing, misappropriating or violating products to territories where we have patent or other intellectual property protection, but enforcement is not as strong as that in the United States. These products may compete with any therapeutic candidates we may develop and our technology and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Additionally, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain jurisdictions, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patent and other intellectual property rights or marketing of competing products in violation of our intellectual property rights generally. For example, an April 2019 report from the Office of the United States Trade Representative identified a number of countries, including China, Russia, Argentina, Chile and India, where challenges to the procurement and enforcement of patent rights have been reported. Proceedings to enforce our or our licensors' patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patent and other intellectual property rights at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and, if we or our licensors prevail, the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. In these jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Issued patents covering any therapeutic candidates we may develop could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Our owned and licensed patent rights may be subject to priority, validity, inventorship and enforceability disputes. If we or our licensors are unsuccessful in any of these proceedings, such patent rights may be narrowed, invalidated or held unenforceable, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or we may be required to cease the development, manufacture and commercialization of one or more of our therapeutic candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering any of any therapeutic candidates we may develop or our technology, the defendant could counterclaim that the patent covering the therapeutic candidate or technology 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, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, interference proceedings, derivation proceedings, post grant review, *inter partes* review and equivalent proceedings such as opposition, invalidation and revocation proceedings in foreign jurisdictions. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover any therapeutic candidates we may develop or our technology or no longer prevent third parties from competing with any therapeutic candidates we may develop or our technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a distraction to management and other employees. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we or our licensing partners were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the

patent protection on one or more of our therapeutic candidates or technology. Such a loss of patent protection could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in patent law in the United States or worldwide could diminish the value of patents in general, thereby impairing our ability to protect any therapeutic candidates we may develop and our technology.

Changes in either the patent laws or interpretation of patent laws in the United States and worldwide, including patent reform legislation such as the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), could increase the uncertainties and costs surrounding the prosecution of any owned or in-licensed patent applications and the maintenance, enforcement or defense of any current in-licensed issued patents and issued patents we may own or in-license in the future. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our in-licensed issued patents and issued patents we may own or in-license in the future, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our therapeutic candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim unpatentable even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to review patentability of our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. As one example, in the case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain

claims to DNA molecules are not patentable simply because they have been isolated from surrounding material. Moreover, in 2012, the USPTO issued a guidance memo to patent examiners indicating that process claims directed to a law of nature, a natural phenomenon or a naturally occurring relation or correlation that do not include additional elements or steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied and the claim amounts to significantly more than the natural principle itself should be rejected as directed to patent-ineligible subject matter. Accordingly, in view of the guidance memo, there can be no assurance that claims in our patent rights covering any therapeutic candidates we may develop or our technology will be held by the USPTO or equivalent foreign patent offices or by courts in the United States or in foreign jurisdictions to cover patentable subject matter. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

If we do not obtain patent term extension and data exclusivity for any therapeutic candidates we may develop, our business may be harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any therapeutic candidates we may develop and our technology, one or more of our U.S. patents that we license or may own in the future may be eligible for limited patent term extension under Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought and within 60 days of FDA approval. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the inventorship or ownership of our patent and other intellectual property rights.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patent rights, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our therapeutic candidates or technology. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patent rights, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to any therapeutic candidates we may develop or our technology. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our therapeutic programs and other proprietary technologies we may develop, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. With respect to our EEV Platform and development programs, we consider trade secrets and know-how to be one of our important sources of intellectual property, including our extensive knowledge of oligonucleotide drug delivery techniques and antibody conjugation. Trade secrets and know-how can be difficult to protect. In particular, the trade secrets and know-how in connection with our EEV Platform, development programs and other proprietary technology we may develop may over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel with scientific positions in academic and industry.

We seek to protect these trade secrets and other proprietary technology, 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, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. 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 inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing our therapeutic candidate. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our therapeutic programs and other proprietary technologies we may develop. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees.

We may not be successful in obtaining necessary rights to any therapeutic candidate we may develop through acquisitions and in-licenses.

We currently own or exclusively license intellectual property rights covering certain aspects of our therapeutic programs. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. In order to avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our therapeutic programs and other proprietary technologies we may develop. 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 therapeutic candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Some of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Furthermore, any disclosure, either intentional or unintentional, by our employees, consultants or vendors, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Such risk of disclosure can be increased by our use of AI technologies and can result in misappropriation and other security incidents and breached. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our 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.

Third-party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators may prevent or delay the development and commercialization of our therapeutic programs and other proprietary technologies we may develop.

Our commercial success depends in part on our ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have also been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are commercializing or plan to commercialize our therapeutic programs and in which we are developing other proprietary technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our therapeutic programs and commercializing activities may give rise to claims of infringement of the patent rights of others. We are aware of third party patents that may cover certain aspects of therapeutic candidates that we are developing or may develop. We cannot assure our stockholders that our therapeutic programs and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our therapeutic programs, might assert as infringed by us. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to our planned products. As such, we review third-party patents in the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe.

In the event that any third party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by us. In this case, the holders of such patents may be able to block our ability to commercialize the infringing products or technologies unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our therapeutic candidate or technologies, which could harm our business significantly. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop our therapeutic candidate and commercialize our product, if approved, which could harm our business significantly. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our

competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

Engaging in litigation defending against third parties alleging infringement of patent and other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. If we do not prevail in the patent proceedings the third parties may assert a claim of patent infringement directed at our therapeutic candidates.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Third parties, such as a competitor, may infringe our patent rights. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable or may refuse to stop the other party from using the invention at issue on the grounds that the patent does not cover the technology in question. In addition, our patent rights may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated or interpreted narrowly. 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.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our therapeutic candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend

significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA or equivalent body. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Furthermore, assertions of potential trademark infringement or possible market confusion may lead to coexistence agreements in order to avoid costly disputes related to our trademarks. As a consequence, we may be forced to amend the list of goods and services covered by our trademarks more narrowly than as originally filed and intended, which could adversely affect our ability to establish name recognition. For example, the description of goods and services for our Entrada trademark was amended twice to settle potential disputes with two other biopharmaceutical companies as part of coexistence agreements. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect 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 our therapeutic candidate or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- we might not have been the first to make the inventions covered by our current or future patent applications;
- we might not have been the first to file patent applications covering our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future patent applications will not lead to issued patents;
- any patent issuing from our current or future patent applications may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties 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 have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- 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 for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

The occurrence of any of these events would have a material adverse effect on our business, financial condition, results of operations and prospects.

We partially depend on intellectual property licensed from third parties, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

We are dependent, in part, on patents, know-how and proprietary technology licensed from others. Our licenses to such patents, know-how and proprietary technology may not provide exclusive rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our therapeutics in the future. The agreements under which

we license patents, know-how and proprietary technology from others are complex, and certain provisions in such agreements may be susceptible to multiple interpretations.

If we fail to comply with obligations under any license agreements, our licensors may have the right to terminate our license, in which event we would not be able to develop or market technology or therapeutic candidates covered by the intellectual property licensed under these agreements. In addition, we may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of therapeutic candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In either event, we may be required to expend significant time and resources to redesign our technology, therapeutic candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology or therapeutic candidates.

If we or our licensors fail to adequately protect our licensed intellectual property, our ability to commercialize therapeutic candidates could suffer. We do not have complete control over the maintenance, prosecution and litigation of our in-licensed patents and patent applications and may have limited control over future intellectual property that may be in-licensed. For example, we cannot be certain that activities such as the maintenance and prosecution by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves, or may not be conducted in accordance with our best interests.

In addition, 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 patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes that may arise between us and our licensors regarding intellectual property subject to a license agreement could include disputes regarding:

- 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 therapeutic candidates 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.

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 technology or therapeutic candidates. As a result, any termination of or disputes over our intellectual property licenses could result in the loss of our ability to develop and commercialize our EEV Platform, or EEV products, or we could lose other significant rights, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

For example, our agreements with certain of our third-party research partners provide that improvements developed in the course of our relationship may be owned solely by either us or our third-party research partner, or jointly between us and the third party. If we determine that rights to such improvements owned solely by a research partner or other third party with whom we collaborate are necessary to commercialize our therapeutic candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing our therapeutic candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our therapeutic candidates or allow our competitors or others the chance to access technology that is important to our business. We also may need the cooperation of any co-owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development portfolio through acquisitions and in-licenses.

The success of our business may depend in part on our ability to acquire, in-license or use third-party proprietary rights. For example, our therapeutic candidates may require specific formulations to work effectively and efficiently, we may develop therapeutic candidates containing our compounds and pre-existing pharmaceutical compounds, or we may be

required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our therapeutic candidates, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patents we may co-own with third parties, we may require licenses to such co-owners interest to such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our therapeutic candidates. More established companies may have a competitive advantage over us due to their size, cash 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. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional therapeutic candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations and prospects could suffer.

We, our collaborators and our service providers may be subject to a variety of privacy and data security laws and contractual obligations, which could increase compliance costs and our failure to comply with them could subject us to potentially significant fines or penalties and otherwise harm our business.

We maintain a large quantity of sensitive information, including confidential business and patient health information in connection with our preclinical studies and clinical trials, and are subject to laws and regulations governing the privacy and security of such information. The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, which adds to the complexity of processing personal data. Guidance on implementation and compliance practices are often updated or otherwise revised.

In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state cybersecurity incident notification laws and federal and state consumer protection laws. Each of these laws is subject to varying interpretations and constantly evolving. By way of example, at the federal level, HIPAA imposes privacy and security requirements and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to the HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations. Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act ("FTCA"), 15 U.S.C § 45(a). The Federal Trade Commission expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

Regulators and legislators in the U.S. are also increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Department of Justice's January 8, 2025, rule on "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons" prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. 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.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, the California Consumer Privacy Act ("CCPA"), which went into effect on January 1, 2020, established a comprehensive privacy framework for covered businesses by creating an expanded definition of personal information, data privacy rights for consumers in the State of California, and special rules on the collection of consumer data from minors. The CCPA also provided for civil penalties for violations of the act, as well as a private right of action for data breaches, which is expected to increase the risk of future data breach litigation. The California Privacy Rights Act ("CPRA") significantly modified the CCPA, imposing additional obligations on companies covered by the legislation, including by creating additional obligations with respect to the processing and storing of personal information and by expanding consumers' rights with respect to certain sensitive information.

Similarly comprehensive privacy laws have been passed in numerous other states, adding additional complexity, variation in requirements, restrictions and potential legal risk, requiring additional investment of resources in compliance programs. The introduction of these laws across the U.S. may impact our strategies and the availability of previously useful data as well as result in increased compliance costs and/or changes in business practices and policies. While these comprehensive consumer state privacy laws incorporate many similar concepts as the CCPA, there are also several key differences in the scope, application, and enforcement of these laws that will change the operational practices of regulated businesses. These comprehensive privacy laws will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests.

Furthermore, in addition to comprehensive privacy laws, certain states have enacted laws which focus on certain specific types of information. For example, Washington's My Health My Data Act, which became effective on March 31, 2024, regulates the collection and sharing of health information and has a private right of action, which further increases the relevant compliance risk. A small number of states have also passed similar laws regulating consumer health data. Further, a small number of states, including Texas and Illinois, have passed laws that regulate biometric information. The existence of these laws as well as comprehensive privacy laws in different states in the country make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. State laws are changing rapidly and there have been discussions in the U.S. Congress of a new comprehensive federal data privacy law to which we could become subject, if enacted.

We will be subject to the data protection laws of the EU and UK in relation to personal data we collect from these territories. These laws impose additional obligations and risk upon our business, including substantial expenses and changes to business operations that are required to comply with these laws. The withdrawal of the UK from the EU (Brexit) and the subsequent separation of the data protection regimes of these territories means we are required to comply with separate data protection laws in the EU and UK which may lead to additional compliance costs and could increase our overall risk. The collection, use, storage, disclosure, transfer, and other processing of personal data in the EU is governed by the provisions of the EU GDPR. Following the withdrawal of the UK from the EU, the UK's European Union (Withdrawal) Act 2018 incorporated the EU GDPR into UK law along with the UK GDPR together with the EU GDPR, referred to as the GDPR. Failure to comply with the GDPR, and Member States' national data protection laws which may apply to the personal data we collect from the European Economic Area ("EEA") or UK, may result in fines and other administrative penalties, including monetary penalties of up to €20/£17.5 million or 4% of worldwide revenue (whichever is higher). 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.

The GDPR imposes several requirements relating to processing personal data, including the requirement to provide notice to individuals about personal data processing activities, ensure an appropriate lawful basis and/or conditions applies to the processing of personal data, having data processing agreements with third parties who process personal data, appointing data protection officers, conducting data protection impact assessments for high risk processing, record-keeping, responding to individuals' requests to exercise their rights in respect of their personal data, notification of data breaches to the competent national data protection authority, and the implementation of safeguards to protect the security

and confidentiality of personal data. The GDPR also imposes several additional requirements relating to the processing of health and other sensitive data which may require us to obtain consent from the individuals to whom the personal data relates.

The GDPR imposes strict rules on the transfer of personal data out of the EEA/UK to countries not regarded by the European Commission and the UK government as providing adequate protection, or third countries, including the United States. These transfers are prohibited unless an appropriate safeguard specified by data protection laws is implemented, such as the Standard Contractual Clauses ("SCCs"), approved by the European Commission, or a derogation applies. Transfers made pursuant to the SCCs need to be assessed on a case-by-case basis to ensure the law in the recipient country provides "essentially equivalent" protections to safeguard the transferred data. If the standard is not met, businesses will be required to adopt supplementary measures. Further, the EU 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 EU and the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. The UK is not subject to the European Commission's SCCs but the UK Information Commissioner's Office has published the UK's own transfer mechanisms for personal data originating from the UK (the International Data Transfer Agreement and International Data Transfer Addendum (each an "IDTA")), which have been in force since March 21, 2022. The IDTA requires the same case-by-case risk assessment of the transfer. In addition, 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. The international transfer obligations under the EEA and UK data protection regimes will require significant effort and cost, and may result in us needing to make strategic considerations around where EEA/UK personal data is located and which service providers we can utilize for the processing of EEA/UK personal data, particularly as the enforcement around GDPR international transfer compliance obligations is currently unclear. The above transfer requirements and other future developments regarding the flow of data across borders could increase the cost and complexity of delivering our services in some markets and may lead to governmental enforcement actions, litigation, fines, and penalties or adverse publicity, which could adversely affect our business and financial position.

Although the UK is regarded as a third country under the EU's GDPR, the European Commission ("EC") has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. In December 2025, the European Commission adopted a decision to extend the validity of the UK adequacy decision for six years until December 2031, determining that the UK continues to offer a level of data protection that is "essentially equivalent" to the EU standards. This follows the UK's adoption of the Data (Use and Access) Act 2025 (the "DUAA") on June 19, 2025. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK Government has confirmed that personal data transfers from the UK to the EEA remain free flowing. 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. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, complexity and cost to our handling of 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.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process. We may be required to modify our data processing practices and policies, put in place additional compliance mechanisms, and utilize management's time and/or divert resources from other initiatives and projects to ensure compliance with new data protection rules. Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

The use of new and evolving technologies, such as AI, in our offerings may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential information, proprietary information and personal information, and as a result we may be exposed to reputational harm and liability.

We, and our third-party vendors, continue to build and integrate AI into our offerings, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect our business. Specifically, risks related to accuracy, bias, AI hallucinations, discrimination,

harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may also experience brand or reputational harm, competitive harm or legal liability.

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. These developments may increase our compliance burden and costs in connection with use of artificial intelligence and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, the EU began implementing the Artificial Intelligence Act (the "AI Act") on August 1, 2024, with a significant part of the law scheduled to come into effect in August 2026. As currently enacted, the AI Act, which may be amended as part of the EU's Digital Omnibus, imposes significant obligations on providers and deployers of high risk 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. The scope of requirements depends on judicial interpretations and forthcoming legislative amendments, and non-compliance can lead to significant fines.

In the U.S., the regulatory environment for AI is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. If we develop or use AI systems that are governed by these laws or regulations, we will need to meet higher standards of data quality, transparency, and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non-compliance. At the federal level, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through an executive order issued December 11, 2025 titled "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that artificial intelligence is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. The use of certain AI technology can give rise to intellectual property risks, including by disclosing or otherwise compromising our confidential or proprietary intellectual property, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of artificial intelligence tools.

Our vendors may in turn incorporate AI tools into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Additionally, the hardware, software, data and cloud computing platforms that we rely on, including, for example, the large language models leveraged in our AI systems, may not continue to be available at reasonable prices, on commercially reasonable terms or at all. Any loss of the right to use any of these hardware, software, data or cloud computing platforms could significantly increase our expenses and disrupt or otherwise result in delays in the provisioning of our services until equivalent technology is either developed by us, or, if available, is identified, obtained through purchase or license and integrated into our services, and no assurance can be provided that such equivalent technology would be developed or obtained in a timely manner or at all. Moreover, as a result of the increasing use and deployment of AI technologies, infrastructure capacity requirements, including network capacity and, computing power and energy requirements, may increase which could lead to an increase in serve interruptions we experience.

Use of open source software could impose limitations on us that may adversely affect our business.

Should use of open source software be necessary for commercialization of our therapeutic candidates, such use could impose limitations on our ability to commercialize. As a result, as we seek to use our platform in connection with commercially available products, we may be required to license software under different license terms, which may not be possible on commercially reasonable terms, if at all. If we are unable to license software components on terms that permit

its use for commercial purposes, we may be required to replace those software components, which could result in delays, additional cost and additional regulatory approvals.

Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the software code. Some open source licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use. If we combine our proprietary software with open source software in a certain manner, we could, under certain of the open source licenses, be required to release the source code of our proprietary software to the public. This could allow our competitors to create similar products with lower development effort and time, and ultimately could result in a loss of product sales for us. Although we monitor our use of open source software, the terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that those licenses could be construed in a manner that could impose unanticipated conditions or restrictions on our ability to commercialize our therapeutic candidates. We could be required to seek licenses from third parties in order to continue offering our therapeutic candidates, to re-engineer our therapeutic candidates or to discontinue the sale of our therapeutic candidates in the event re-engineering cannot be accomplished on a timely basis, any of which could materially and adversely affect our business, financial condition, results of operations and prospects.

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

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover our trade secrets or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on certain third parties to manufacture all or part of our drug product and to perform quality testing, and because we collaborate with various organizations and academic institutions for the advancement of our product engine and development portfolio, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements and other similar agreements with our collaborators, advisors, employees, consultants and contractors prior to beginning research or disclosing any proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets by third parties. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's or other third party's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may harm our business, financial condition, results of operations and prospects.

Rights to improvements to our therapeutic candidates may be held by third parties.

In the course of testing our therapeutic candidates, we may enter into agreements with third parties to conduct clinical testing, which may provide that improvements to our therapeutic candidates may be owned solely by a party or jointly between the parties. If we determine that rights to such improvements owned solely by a third party are necessary to commercialize our therapeutic candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing the therapeutic candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby giving our competitors and other third parties access to the same technologies licensed to us. Failure to obtain a license on commercially reasonable terms or at all, or to obtain an exclusive license, could prevent us from commercializing our therapeutic candidates or force us to cease some of our business operations, which could materially harm our business. If we determine that rights to improvements jointly owned between us and a third party are necessary to commercialize our therapeutic candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such improvements, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our therapeutic candidate, and other proprietary technologies. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Risks Related to Ownership of Our Common Stock

We do not know whether an active, liquid and orderly trading market will be sustained for our common stock and as a result it may be difficult for our stockholders to sell their shares of our common stock.

Although our common stock is listed on the Nasdaq Global Market, an active trading market for our common stock may not be sustained. If a market for our common stock is not sustained, it may be difficult for our stockholders to sell their shares at the time they wish to sell them or at a price that they consider reasonable. The lack of a sustained active market may also reduce the fair market value of our stockholders' shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration.

Recent volatility in capital markets and lower market prices for many securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.

Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our strategic goals, including near-term value creation and workforce capability evolution, respond to business challenges or opportunities, develop new solutions, improve our existing solutions, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements;
- develop or enhance our technological infrastructure and our existing solutions;
- pursue acquisitions or other strategic relationships; and
- respond to competitive pressures.

Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our business.

The market price of our common stock may be volatile, and investors could lose all or part of their investment.

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and 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.

Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report, these factors include:

- the timing and results of INDs, preclinical studies and clinical trials of our therapeutic candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- any delay in our regulatory filings for our therapeutic candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings;
- adverse developments concerning our potential future in-house manufacturing facilities or CMOs;
- regulatory actions with respect to our therapeutics or therapeutic candidates or our competitors' products or therapeutic candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- the size and growth of our initial target markets;
- unanticipated serious safety concerns related to the use of our therapeutic candidates;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- significant lawsuits, including patent or stockholder litigation;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;
- the impact of any natural disasters or public health emergencies;
- general macroeconomic, geopolitical, industry and market conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, tariffs (including tariffs that have been or may in the future be imposed by the United States or other countries), sanctions, trade protection measures or other trade barriers (including further legislation or actions taken by the United States or other countries that restrict trade), social, political and economic risks and military acts of war or terrorism; and
- other events or factors, many of which are beyond our control.

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 adverse impact on the market price of our common stock.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. In the event that one or more of the analysts who covers us issues adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our failure or perceived failure to achieve our corporate sustainability goals or maintain corporate sustainability practices that meet evolving stakeholder expectations could adversely affect us.

Our ability to achieve published corporate sustainability goals and commitments is subject to numerous factors both within and outside of our control. Our failure or perceived failure to achieve our corporate sustainability goals or maintain corporate sustainability practices that meet stakeholder expectations or regulatory requirements could harm our reputation, adversely impact our ability to attract and retain employees or customers and expose us to increased scrutiny from the investment community, regulatory authorities and others or subject us to liability. Our reputation also may be harmed by the perceptions that our customers, employees and other stakeholders have about our action or inaction on corporate sustainability issues. In addition, the increasing prevalence of corporate sustainability laws and regulations across the jurisdictions in which we operate may increase compliance risks and costs and, together with differing views on the appropriate role of sustainability practices and disclosures, may subject us to greater stakeholder scrutiny. Any potential damage to our reputation or loss of brand equity may adversely impact our business.

Unstable market and global economic conditions, political instability and geopolitical events may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. For example, inflation generally affects us by increasing our employee-related costs and clinical trial expenses, as well as other operating expenses. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our business could also be impacted by volatility caused by geopolitical events within the United States and foreign jurisdictions, including as a result of an economic downturn and geopolitical events, such as changes in the U.S. federal policy that affect the geopolitical landscape and ongoing military conflicts, such as the recent conflict in Iran, as well as ongoing conflicts in Ukraine and in the Middle East. Although the length and impact of the ongoing military conflicts is highly unpredictable, the ongoing conflicts between Russia and Ukraine, the U.S. and Iran, and in the Middle East have led to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions, which contributed to record inflation globally. We are continuing to monitor inflation, the situations in Ukraine and the Middle East and global capital markets and assessing their potential impact on our business, including the impact on the supply chains we rely on for the manufacture of our product and product candidates and related raw materials. Sanctions imposed by the U.S. and other countries in response to such conflicts may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. Additionally, changes to 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, on October 1, 2025, the U.S. federal government shutdown through November 12, 2025, suspending services deemed non-essential as a result of the failure by Congress to enact regular appropriations for the 2026 fiscal year. If we experience another prolonged government shutdown, it could result in increased uncertainty and volatility in the global economy and financial markets which could have a material adverse effect on our business. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur, including as a result of heightened geopolitical tensions or increasing concerns regarding a potential global recession. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive.

Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse event on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. For example, the BIOSECURE Act, signed into law as part of the recently-enacted NDAA, may restrict the ability of U.S. biopharmaceutical companies to purchase services or products from, or otherwise

collaborate with, certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We continue to assess the legislation as it develops to determine whether it could have an effect on our contractual relationships. Also, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. To the extent that our profitability and strategies are negatively affected by downturns or volatility in general economic conditions, our business and results of operations may be materially adversely affected.

Our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Our business is affected by macroeconomic conditions, including inflationary pressure, tariffs, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates, tariffs and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on our 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.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 60% of our outstanding voting stock as of September 30, 2026. These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that investors may feel are in their best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with each investor's interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our 2021 Plan and 2025 Inducement Equity Plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, supporting commercialization efforts, expanding research and development activities for key preclinical programs and covering costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to our 2021 Stock Option and Incentive Plan, as amended (the "2021 Plan"), our management is authorized to grant stock options to our employees, directors and consultants. Additionally, pursuant to our 2025 Inducement Equity Plan, as amended (the "2025 Inducement Plan"), our board of directors or compensation committee of the board of directors are authorized to grant equity awards to induce highly qualified prospective employees who are not currently employed by the Company to accept employment with the Company. If the number of shares reserved under our 2021 Plan and/or the 2025 Inducement Plan is increased pursuant to the terms of the 2021 Plan and the 2025 Inducement Plan, as applicable, our stockholders may experience additional dilution, which could cause our stock price to fall.

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.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or therapeutic candidates.

We do not have any committed external source of funds or other support for our development and commercialization efforts, and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, including potentially through our at-the-market offering program, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Any future debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

As a result of our recurring losses from operations and recurring negative cash flows from operations, there is substantial doubt about our ability to continue as a going concern. If we raise additional funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs, therapeutic candidates or EEV Platform, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market therapeutic candidates that we would otherwise prefer to develop and market ourselves. 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.

We are an "emerging growth company" and a smaller reporting company and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley Act");
- not being required to comply 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;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these

exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions.

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

We have never declared or paid any cash dividends on our common 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 any appreciation in the value of their stock.

Anti-takeover provisions in our certificate of incorporation, our bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our Fourth Amended and Restated Certificate of Incorporation, as amended ("Charter"), and our Amended and Restated Bylaws ("Bylaws") contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions include, among other things:

- 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 actions through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders 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;
- 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 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 two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action;
- a requirement of approval by the affirmative vote of a majority of the outstanding shares of our voting stock to amend or repeal specified provisions of our certificate of incorporation, and the affirmative vote of a majority of the outstanding shares of each class entitled to vote thereon as a class, at a duly constituted meeting of stockholders called expressly for such purpose; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, Section 203 of the General Corporation Law of the State of Delaware ("DGCL") prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our Charter, our Bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our Bylaws designate certain courts 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 Bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any

provision of the DGCL, our certificate of incorporation or our bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein ("Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our Bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act ("Federal Forum Provision"). In addition, our Bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the 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, the forum selection clauses in our Bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such 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 were "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 U.S. 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.

General Risk Factors

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to related compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we cease to be an "emerging growth company" effective as of December 31, 2026, the last day of the fiscal year following the fifth anniversary of the closing of our IPO. Beginning with our Annual Report on Form 10-K for the year ending December 31, 2026, we will no longer be able to take advantage of the exemptions available to emerging growth companies, including the extended transition period for adopting new or revised accounting standards, and we will become subject to additional disclosure and compliance requirements, including holding nonbinding advisory votes on executive compensation. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel devote and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase our operating expenses. For example, we expect these rules and regulations to 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 sufficient coverage, particularly in light of recent cost increases related to coverage. We cannot accurately 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 qualified persons to serve on our board of directors, our board committees or as executive officers.

In addition, as a public company, we are required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, beginning with our second annual report on Form 10-K after we became a public company, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we may be required, for as long as we are an accelerated filer or a large accelerated filer, to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm, beginning with our Annual Report on Form 10-K for the year ending December 31, 2026. Preparing for and obtaining this attestation will require additional costs and management attention, and our independent registered public accounting firm may identify deficiencies in our internal control over financial reporting that we did not identify in our own assessment. To achieve compliance with Section 404, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed

and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We may in the future discover material weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

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

We are subject to the periodic reporting requirements of the Exchange Act. 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 facts 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.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employment benefits liability, business automobile, workers' compensation, and directors' and officers', employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

Disruptions at the FDA, the SEC and other U.S. government agencies caused by reduction in staffing, funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

Federal agencies in the U.S., including the FDA, the SEC and other comparable regulatory authorities, operate pursuant to annual appropriations and other political and budgetary processes, and may from time to time be subject to continuing resolutions, funding lapses, or other fiscal restraints. The FDA is currently funded through December 11, 2026. The ability of the FDA and other comparable regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, leadership and policy changes, the FDA's or other comparable regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or other comparable regulatory authorities' ability to

perform routine functions. Average review times at the FDA and other comparable regulatory authorities have fluctuated in recent years and may continue to fluctuate as a result of these factors. In addition, government funding of the SEC and other U.S. government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, including executive and congressional priorities, which is inherently fluid and unpredictable. For example, the Trump Administration has issued executive orders seeking to greatly reduce the size of the federal workforce, including through layoffs and severance packages offered to employees of federal agencies within the executive branch and independent agencies, including the FDA. Any such reduction in personnel may result in longer review times by the FDA and other agencies.

Disruptions and personnel turnover, as a result of leadership changes, staff reductions or otherwise at the FDA, the SEC and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in 2025, changes and cuts in FDA staffing have been reported as resulting in delays in the FDA's responsiveness or in its ability to review IND submissions or marketing applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Also, state governments may seek to address or react to changes at the federal level with changes to their regulatory frameworks in a manner that could impact our operations.

Over the last several years, including from October 1, 2025 to November 12, 2025, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs again, or a widespread freeze on federal funding occurs in the future or if global health concerns or staffing changes prevent the FDA, the SEC or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including formal and informal interactions with product developers, it could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our future regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns and/or substantial leadership, personnel, and policy changes at the SEC could impact our business be delaying review of our public filings, which in turn could delay our frustrate our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations or delay the review or effectiveness of required regulatory or securities filings.

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

Set forth below is information regarding shares of equity securities sold, and options granted, by us during the three months ended September 30, 2026 that were not registered under the Securities Act of 1933, as amended (the "Securities Act").

Recent Sales of Unregistered Equity Securities

None.

Purchase of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Rule 10b5-1 Trading Arrangements

From time to time, our officers (as defined in Rule 16a–1(f)) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the three months ended September 30, 2026, none of our officers or directors adopted or terminated contracts, instructions or written plans

for the purchase or sale of our securities that are intended to satisfy the conditions specified in Rule 10b5-1(c) under the Exchange Act for an affirmative defense against liability for trading in securities on the basis of material nonpublic information.

Item 6. Exhibits

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report on Form 10-Q ("Quarterly Report").

Exhibit No.	Description
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by the Registrant on November 2, 2021).
3.2	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by the Registrant on June 13, 2024).
3.3	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed by the Registrant on November 2, 2021).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 filed by the Registrant on October 25, 2021).
4.2	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, effective as of March 29, 2021 (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 filed by the Registrant on October 8, 2021).
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by the Registrant on June 24, 2024).
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 Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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 Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†+	Certifications 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 its XBRL tags are embedded within the Inline XBRL document
101.SCH†	Inline XBRL Taxonomy Extension Schema Document
101.CAL†	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF†	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB†	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE†	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104†	Cover Page Interactive Data File (formatted in as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

† Filed herewith.

+ The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report 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, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 5, 2026

ENTRADA THERAPEUTICS, INC.

By:	/s/ Dipal Doshi
Name:	Dipal Doshi
Title:	Chief Executive Officer and Director (Principal Executive Officer)

By:	/s/ Kory Wentworth
Name:	Kory Wentworth
Title:	Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dipal Doshi, certify that:

1. I have reviewed this Form 10-Q for the quarterly period ended September 30, 2026 of Entrada 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 5, 2026

By: /s/ Dipal Doshi

Dipal Doshi
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kory Wentworth, certify that:

1. I have reviewed this Form 10-Q for the quarterly period ended September 30, 2026 of Entrada 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 5, 2026

By: /s/ Kory Wentworth

Kory Wentworth
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS 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

In connection with the Quarterly Report on Form 10-Q of Entrada Therapeutics, Inc. (the "Company") for the quarterly period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of their knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 5, 2026

By: /s/ Dipal Doshi

Dipal Doshi
Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2026

By: /s/ Kory Wentworth

Kory Wentworth
Chief Financial Officer
(Principal Financial and Accounting Officer)