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 001-39782

4D Molecular Therapeutics, Inc.

(Exact name of registrant as specified in its Charter)

Delaware	**47-3506994**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5858 Horton Street #455 Emeryville, CA	**94608**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (510) 505-2680

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	FDMT	The Nasdaq Global Select Market

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

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

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

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

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

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

As of November 9, 2026, there were 56,379,402 shares of 4D Molecular Therapeutics, Inc.'s common stock outstanding. This number does not include 16,004,945 shares of common stock issuable upon the exercise of pre-funded warrants outstanding as of November 9, 2026 (which are immediately exercisable at an exercise price of $0.0001 per share of common stock, subject to beneficial ownership limitations).

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of 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 forward-looking statements concern our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our development activities, preclinical studies and clinical trials, including our preclinical and clinical trials for 4D-150, 4D-175, 4D-710 and 4D-725;
- the number, size and design of our planned clinical trials, and what regulatory authorities may require to obtain marketing approval;
- the timing of Investigational New Drug Application (“IND”) enabling studies and results from such studies;
- the timing and success of lead optimization for our product candidates;
- the translation of our preclinical results and data into future clinical trials in humans;
- the timing of any manufacturing runs for materials to be used in patient trials;
- the timing or likelihood of regulatory filings and approvals;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize our product candidates;
- our ability to comply with restrictive covenants under our loan and security agreement (the "Loan and Security Agreement") with Hercules Capital, Inc.;
- our ability to satisfy interest and principal payments under the Loan and Security Agreement;
- the rate and degree of market acceptance of our product candidates, if approved;
- the success of competing products or platform technologies that are or may become available;
- our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain approval;
- future agreements with third parties in connection with the commercialization of our product candidates;
- the size and growth potential of the markets for our product candidates, if approved for commercial use, and our ability to serve those markets;
- existing regulations and regulatory developments in the United States and foreign countries;
- the expected potential benefits of strategic collaboration agreements, including our relationships with Otsuka Pharmaceutical Co., Ltd. and the Cystic Fibrosis Foundation, and our ability to attract collaborators with development, regulatory and commercialization expertise;

- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- potential claims relating to our intellectual property and third-party intellectual property;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the pricing and reimbursement of our product candidates, if approved;
- the potential effects of public health emergencies on our preclinical and clinical programs and our business;
- our ability to attract and retain key managerial, scientific and medical personnel;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing; and
- our financial performance.

These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be inaccurate. 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 on Form 10-Q. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks we describe in the reports we file from time to time with the SEC after the date of this Quarterly Report on Form 10-Q.

Risk Factor Summary

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. The following is a summary of the principal risks that could seriously harm our business, all of which are more fully described in Part II. Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q. This summary should be read in conjunction with the discussion of risk factors in Part II, Item 1A of this Quarterly Report on Form 10-Q, and should not be relied upon as an exhaustive summary of the material risks facing our business.

- We are in the late stages of drug development for our lead program and have a limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.
- We have had recurring net losses, and we expect to continue to incur significant net losses for the foreseeable future.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

- All of our product candidates are based on a novel AAV genetic medicine technology with which there is limited regulatory and clinical experience to date, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval. Further, the regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied therapeutic modalities.
- Adverse public perception or regulatory scrutiny of genetic medicine technology may negatively impact the developmental progress or commercial success of product candidates that we develop alone or with collaborators.
- Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization, which could seriously harm our business.
- Gene therapies are novel, complex and difficult to manufacture. We could experience production problems that result in delays in our development or commercialization programs, limit the supply of our products or otherwise seriously harm our business.
- The regulatory approval processes of the U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") and comparable foreign regulatory authorities are lengthy, expensive, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of licenses granted to us by others, and the patent protection, prosecution and enforcement for some of our product candidates may be dependent on our licensors.
- Our employees, independent contractors, consultants, research or commercial partners or collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

PART I. FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

4D Molecular Therapeutics, Inc.
Condensed Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 39,104	$ 60,241
Marketable securities	267,885	342,414
Collaboration receivable	4,021	—
Prepaid expenses and other current assets	11,276	10,479
Total current assets	322,286	413,134
Marketable securities, long-term	68,044	111,379
Property and equipment, net	11,224	14,867
Operating lease right-of-use assets, net	15,758	18,143
Other non-current assets	11,437	9,188
Total assets	$ 428,749	$ 566,711
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 7,882	$ 11,159
Accrued and other current liabilities	35,211	26,874
Deferred revenue	360	360
Deferred grant reimbursements	3,631	—
Operating lease liabilities, current portion	5,310	5,592
Total current liabilities	52,394	43,985
Deferred revenue, net of current portion	2,830	745
Derivative liability	397	358
Operating lease liabilities, long-term portion	13,424	15,821
Long-term debt	19,679	—
Other liabilities	2,082	138
Total liabilities	90,806	61,047
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized at September 30, 2026 and December 31, 2025; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized at September 30, 2026 and December 31, 2025; 56,374,519 and 57,607,874 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	6	6
Additional paid-in-capital	1,274,998	1,221,235
Accumulated other comprehensive gain (loss)	(1,005)	727
Accumulated deficit	(936,056)	(716,304)
Total stockholders' equity	337,943	505,664
Total liabilities and stockholders' equity	$ 428,749	$ 566,711

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

4D Molecular Therapeutics, Inc.
Condensed Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Collaboration and license revenue	$ 4,145	$ 90	$ 10,974	$ 119
Operating expenses:				
Research and development	69,776	49,438	203,038	138,088
General and administrative	15,587	11,837	39,798	36,293
Total operating expenses	85,363	61,275	242,836	174,381
Loss from operations	(81,218)	(61,185)	(231,862)	(174,262)
Other income (expense):				
Interest income	3,943	4,330	13,062	14,771
Other income (expense), net	(781)	(21)	(951)	(15)
Total other income, net	3,162	4,309	12,111	14,756
Net loss	$ (78,056)	$ (56,876)	$ (219,751)	$ (159,506)
Net loss per share, basic and diluted	$ (1.08)	$ (1.01)	$ (3.13)	$ (2.85)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	72,251,127	56,126,330	70,211,785	55,933,890

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

4D Molecular Therapeutics, Inc.
Condensed Statements of Comprehensive Loss
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net loss	$ (78,056)	$ (56,876)	$ (219,751)	$ (159,506)
Other comprehensive loss:				
Net unrealized gain (loss) on marketable securities	(559)	334	(1,732)	442
Total comprehensive loss	$ (78,615)	$ (56,542)	$ (221,483)	$ (159,064)

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

4D Molecular Therapeutics, Inc.
Condensed Statements of Stockholders' Equity
(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2025	57,607,874	$ 6	$ 1,221,235	$ 727	$ (716,304)	$ 505,664
Issuance of common stock upon exercise of stock options and vesting of RSUs	251,629	—	1,674	—	—	1,674
Issuance of common stock upon ATM offering, net of issuance costs	1,012,145	—	9,712	—	—	9,712
Exchange of common stock for pre-funded warrants	(6,600,000)	(1)	1	—	—	—
Stock-based compensation expense	—	—	4,453	—	—	4,453
Net unrealized loss on marketable securities	—	—	—	(907)	—	(907)
Net loss	—	—	—	—	(68,760)	(68,760)
Balances at March 31, 2026	52,271,648	$ 5	$ 1,237,075	$ (180)	$ (785,064)	$ 451,836
Issuance of common stock upon exercise of stock options and vesting of RSUs	67,640	—	111	—	—	111
Issuance of common stock - 2020 ESPP	368,482	—	1,125	—	—	1,125
Issuance of common stock upon ATM offering, net of issuance costs	2,506,327	1	21,904	—	—	21,905
Stock-based compensation expense	—	—	5,884	—	—	5,884
Net unrealized loss on marketable securities	—	—	—	(266)	—	(266)
Net loss	—	—	—	—	(72,936)	(72,936)
Balances at June 30, 2026	55,214,097	$ 6	$ 1,266,099	$ (446)	$ (858,000)	$ 407,659
Issuance of common stock upon exercise of stock options and vesting of RSUs	229,710	—	642	—	—	642
Stock-based compensation expense	—	—	8,257	—	—	8,257
Issuance of common stock upon exercise of pre-funded warrants	930,712	—	—	—	—	—
Net unrealized loss on marketable securities	—	—	—	(559)	—	(559)
Net loss	—	—	—	—	(78,056)	(78,056)
Balances at September 30, 2026	56,374,519	$ 6	$ 1,274,998	$ (1,005)	$ (936,056)	$ 337,943

Continued on next page.

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2024	45,793,942	$ 5	$ 1,086,567	$ 229	$ (576,195)	$ 510,606
Issuance of common stock upon exercise of stock options and vesting of RSUs	22,235	—	—	—	—	—
Issuance of common stock upon exercise of equity warrants	508,465	—	—	—	—	—
Stock-based compensation expense	—	—	6,986	—	—	6,986
Net unrealized gain on marketable securities	—	—	—	103	—	103
Net loss	—	—	—	—	(47,972)	(47,972)
Balances at March 31, 2025	46,324,642	$ 5	$ 1,093,553	$ 332	$ (624,167)	$ 469,723
Issuance of common stock upon exercise of stock options and vesting of RSUs	49,791	—	2	—	—	2
Issuance of common stock - 2020 ESPP	323,290	—	860	—	—	860
Issuance of common stock upon exercise of service warrants	2,519	—	—	—	—	—
Stock-based compensation expense	—	—	4,958	—	—	4,958
Net unrealized gain on marketable securities	—	—	—	5	—	5
Net loss	—	—	—	—	(54,658)	(54,658)
Balances at June 30, 2025	46,700,242	$ 5	$ 1,099,373	$ 337	$ (678,825)	$ 420,890
Issuance of common stock upon exercise of stock options and vesting of RSUs	70,943	—	116	—	—	116
Stock-based compensation expense	—	—	4,519	—	—	4,519
Net unrealized gain on marketable securities	—	—	—	334	—	334
Net loss	—	—	—	—	(56,876)	(56,876)
Balances at September 30, 2025	46,771,185	$ 5	$ 1,104,008	$ 671	$ (735,701)	$ 368,983

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

4D Molecular Therapeutics, Inc.
Condensed Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine months ended September 30,	
	2026	**2025**
Cash flows from operating activities		
Net loss	$ (219,751)	$ (159,506)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	18,594	16,463
Change in fair value of derivative liability	39	(65)
Depreciation and amortization	3,764	3,478
Loss on disposal of property and equipment	51	—
Amortization of right-of-use assets	2,385	2,167
Net accretion of discount on marketable securities	(3,242)	(3,587)
Noncash interest expense on long-term debt	92	—
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(4,484)	2,741
Other non-current assets	(2,067)	(5,119)
Accounts payable	(3,466)	2,477
Accrued and other liabilities	13,844	5,780
Deferred revenue	2,085	(119)
Operating lease liabilities	(2,679)	(2,343)
Net cash used in operating activities	(194,835)	(137,633)
Cash flows from investing activities		
Purchases of marketable securities	(180,384)	(264,721)
Maturities of marketable securities	299,759	301,201
Acquisition of property and equipment	(104)	(606)
Net cash provided by investing activities	119,271	35,874
Cash flows from financing activities		
Issuance of common stock upon exercise of stock options	2,427	118
Issuance of common stock under the ATM offering program, net of issuance costs	31,616	—
Issuance of common stock - 2020 ESPP	1,125	860
Proceeds from long-term debt, net of discount and issuance costs	19,259	—
Net cash provided by financing activities	54,427	978
Net decrease in cash and cash equivalents	(21,137)	(100,781)
Cash and cash equivalents, beginning of period	60,241	149,336
Cash and cash equivalents, end of period	$ 39,104	$ 48,555
Supplemental disclosures of noncash investing and financing information		
Purchases of property and equipment in accounts payable and accrued and other current liabilities	$ 67	$ —

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

4D Molecular Therapeutics, Inc.
Notes to Condensed Financial Statements
(Unaudited)

1. The Company

4D Molecular Therapeutics, Inc. (the "Company") was formed as a limited liability company in September 2013 under the name 4D Molecular Therapeutics, LLC. The Company changed its name and converted into a corporation which was incorporated in the state of Delaware in March 2015. The Company is a late-stage biotechnology company advancing durable and disease-targeted therapeutics with potential to transform treatment paradigms and provide benefits to patients.

2025 Offering

In November 2025, the Company completed an underwritten offering (the "2025 Offering") in which 8,385,809 shares of the Company's common stock were sold at an offering price of $10.51 per share, as well as pre-funded warrants to purchase 1,128,949 shares of the Company's common stock at an offering price of $10.5099 per underlying share pursuant to an effective Registration Statement on Form S-3. The net proceeds from the 2025 Offering were approximately $93.3 million, after deducting the underwriting discounts and commissions and other offering expenses.

Liquidity

The Company has incurred significant losses and negative cash flows from operations and had an accumulated deficit of $936.1 million as of September 30, 2026. The Company believes that its cash, cash equivalents and marketable securities as of September 30, 2026 are sufficient for the Company to fund planned operations for at least one year from the issuance date of these condensed financial statements. The Company has funded its operations primarily through the sale and issuance of equity securities, including primary follow-on offerings and use of the Company's "at-the-market" offering program, from borrowings under the Company's $200.0 million loan facility (the "Loan and Security Agreement") with Hercules Capital, Inc. ("Hercules") (see Note 9, Long-Term Debt) and, to a lesser extent, from cash received pursuant to its collaboration and license agreements. To date, none of the Company's product candidates have been approved for sale, and therefore, the Company has not generated any revenue from product sales. Management expects operating losses and negative cash flows from operations to continue for the foreseeable future. The Company plans to raise additional funding as required based on the status of its clinical trials and projected cash flows. There can be no assurance that, in the event the Company requires additional financing, such financing will be available on terms acceptable to the Company, if at all. Failure to generate sufficient cash flows from operations, raise additional capital or reduce discretionary spending should additional capital not become available could have a material adverse effect on the Company's ability to achieve its business objectives.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed financial statements have been prepared in accordance with United States Generally Accepted Accounting Principles ("U.S. GAAP") and the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim reporting.

Certain information and note disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. Accordingly, the condensed financial statements should be read in conjunction with the audited financial statements and the related notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC.

The accompanying financial information for the three and nine months ended September 30, 2026 and 2025 is unaudited. The condensed financial statements have been prepared on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of the Company's financial position as of September 30, 2026, and its results of operations and cash flows for the three and nine months ended September 30, 2026 and 2025. The condensed balance sheet at December 31, 2025 was derived from audited annual financial statements but does not contain all of the footnote disclosures from the annual financial statements. The results for interim periods are not necessarily indicative of the results expected for the full fiscal year or any other periods.

Use of Estimates and Judgments

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses; and disclosure of contingent assets and liabilities as of the date of the financial statements. Such estimates include the determination of useful lives for property and equipment, the contract term, transaction price and costs of collaboration agreements, stock options, the derivative instrument, long-term debt and income tax uncertainties. Actual results could differ from those estimates.

Due to the war in Ukraine, conflicts in the Middle East, any expansion of these conflicts, rising interest rates, tariffs and inflation, natural disasters and health crises, such as pandemics, there has been uncertainty and disruption in the global economy and financial markets. The Company is not aware of any specific event or circumstance that would require an update to its estimates or judgments or a revision of the carrying value of its assets or liabilities as of September 30, 2026. While there was not a material impact to the Company's condensed financial statements as of September 30, 2026, these estimates may change, as new events occur and additional information is obtained, as well as other factors that could result in material impacts to the condensed financial statements in future reporting periods.

Long-Term Debt

Long-term debt is recognized at cost and presented net of the original issue discount or premium and debt issuance costs on the condensed balance sheets. Amortization of debt discount and debt issuance costs is recognized as interest expense over the period of the debt, using the effective interest rate method. See Note 9, Long-Term Debt, for further discussion of the long-term debt.

Segment Information

The Company manages its business as one segment which includes all activities related to the discovery, development, and commercialization of medicines for specific diseases. See Note 20, Segment Information, for financial information related to the Company's one segment.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, marketable securities and accounts receivable. The Company's cash is held at two financial institutions in the United States of America. The Company's cash equivalents are invested in money market funds. The Company also invests in U.S. Treasuries, U.S. government sponsored agencies, commercial paper, corporate bonds and certificates of deposit. The Company has not experienced any losses on its deposits of cash and cash equivalents. Such deposits may, at times, exceed federally insured limits.

The Company's partners in collaboration and license agreements who represent 10% or more of the Company's total revenue are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Otsuka Pharmaceutical Co., Ltd.	98%	0%	98%	0%
Cystic Fibrosis Foundation	*	100%	*	100%
Total	98%	100%	98%	100%

* Less than 10%

As of September 30, 2026, the Company had $4.0 million due from Otsuka Pharmaceutical Co., Ltd. ("Otsuka") related to the estimated cost sharing and reimbursement. The Company did not have accounts receivable from its other partner in collaboration and license agreements as of September 30, 2026 and December 31, 2025.

The Company's total revenues by geographic region, based on the location of the customer, are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Japan	$ 4,055	$ —	$ 10,704	$ —
United States	90	90	270	119
Total	$ 4,145	$ 90	$ 10,974	$ 119

Other Risks and Uncertainties

The Company is subject to risks and uncertainties common to late clinical-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, suppliers for key raw materials, contract development and manufacturing organizations ("CDMOs") and contract research organizations ("CROs"), compliance with government regulations and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies, clinical trials and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance and reporting.

There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from other pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, consultants and other third parties (including for clinical trials and some aspects of research and preclinical testing).

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update ("ASU") No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Topic 220) - Disaggregation of Income Statement Expenses*. ASU 2024-03 requires public business entities to disclose, on an annual and interim basis, disaggregated information about certain income statement expense line items in the notes to the financial statements. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026 (fiscal 2027) and interim periods within fiscal years beginning after December 15, 2027 (fiscal 2028). The ASU must be applied prospectively and may be applied retrospectively if elected. The Company is currently evaluating the effect of adopting this new accounting guidance.

In September 2025, the FASB issued ASU No. 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software.* The amendments to ASU 2025-06 remove all references to prescriptive and sequential software development stages. The amendments to ASU 2025-06 require entities to begin capitalizing software costs when management authorizes and commits to funding the software project, and it is probable that the project will be completed and the software will be used for its intended purpose. ASU 2025-06 is effective for fiscal years beginning after December 15, 2027, with early adoption permitted. The ASU may be applied on a fully prospective basis, a modified basis for in-process projects or a full retrospective basis. The Company is currently evaluating the effect of adopting this new accounting guidance.

Recently Issued Accounting Pronouncements Adopted

In December 2025, the FASB issued ASU 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities*. The Company early adopted ASU 2025-10 as of January 1, 2026 using the modified prospective transition approach. The adoption did not have a material impact on the Company's condensed financial statements. See Note 17, *California Institute for Regenerative Medicine Award*, for additional information regarding the Company's accounting for government grants.

3. Fair Value Measurements and Marketable Securities

The following tables represent the Company’s fair value hierarchy for financial assets measured at fair value on a recurring basis (in thousands):

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value as of September 30, 2026	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Assets							
Cash	$ 7,261	$ —	$ —	$ 7,261	$ 7,261	$ —	$ —
Level 1:							
Money market funds	24,867	—	—	24,867	24,867	—	—
Level 2:							
Certificates of deposit	11,320	—	(14)	11,306	—	11,306	—
Commercial paper	91,624	1	(147)	91,478	6,976	84,502	—
U.S. Treasuries	62,286	—	(397)	61,889	—	37,645	24,244
Corporate bonds	178,680	13	(461)	178,232	—	134,432	43,800
Subtotal	343,910	14	(1,019)	342,905	6,976	267,885	68,044
Total	$ 376,038	$ 14	$ (1,019)	$ 375,033	$ 39,104	$ 267,885	$ 68,044

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value as of December 31, 2025	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Assets							
Cash	$ 10,696	$ —	$ —	$ 10,696	$ 10,696	$ —	$ —
Level 1:							
Money market funds	39,570	—	—	39,570	39,570	—	—
Level 2:							
Certificates of deposit	35,986	37	—	36,023	—	36,023	—
Commercial paper	63,875	48	—	63,923	5,479	58,444	—
U.S. Treasuries	76,920	153	—	77,073	—	63,589	13,484
Corporate bonds	286,260	492	(3)	286,749	4,496	184,358	97,895
Subtotal	463,041	730	(3)	463,768	9,975	342,414	111,379
Total	$ 513,307	$ 730	$ (3)	$ 514,034	$ 60,241	$ 342,414	$ 111,379

There are no Level 3 assets and no Level 1 or 2 liabilities.

All marketable securities held as of September 30, 2026 had contractual maturities of less than two years. There have been no material realized gains or losses on marketable securities for the periods presented.

Aggregate fair values of marketable securities with unrealized losses and gains were as follows as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026	December 31, 2025
Aggregate fair value of marketable securities in a continuous loss position for less than twelve months	$ 293,255	$ 15,449
Aggregate fair value of marketable securities in a continuous loss position for more than twelve months	—	1,951
Aggregate fair value of marketable securities in unrealized gain position	35,074	446,368
Aggregate fair value of marketable securities in neither an unrealized loss nor an unrealized gain position	7,600	—
Total marketable securities	$ 335,929	$ 463,768

The Company manages credit risk associated with its investment portfolio through its investment policy, which limits purchases to high-quality issuers and also limits the amount of its portfolio that can be invested in a single issuer. The Company did not record an allowance for credit losses or other impairment charges related to its marketable securities for any period presented. The Company has determined that (i) it does not have the intent to sell any of these investments, and (ii) it is not more likely than not that it will be required to sell any of these investments before recovery of the entire amortized cost basis. The Company further considered the maximum unrealized loss amounts both at the individual instrument level and in aggregate as immaterial as of September 30, 2026. These unrealized losses were not attributed to credit risk and were associated with changes in market conditions. The Company periodically reviews its marketable securities for indications of credit losses. The Company anticipates that it will recover the entire amortized cost basis of such securities, and therefore, no credit loss existed as of September 30, 2026.

Level 3 Inputs

The fair value of the derivative liability is based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The fair value of the derivative liability was determined using a present value analysis with multiple scenarios. In determining the fair value of the derivative liability, the inputs impacting fair value include the change of control payment to the Cystic Fibrosis Foundation, the probability of a change of control event, the product status at time of a change of control event and the discount rate. See Note 6, Research and Collaboration Arrangements, and Note 16, Derivative Liability, for further discussion of the embedded derivative.

There were no transfers between Level 1, 2 and 3 for assets or liabilities during the periods presented.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instrument (in thousands):

	Derivative Liability
Balance as of December 31, 2025	$ 358
Change in fair value	39
Balance as of September 30, 2026	$ 397

The change in fair value above is included in other income (expense), net, in the Company's condensed statements of operations.

4. Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Machinery and equipment	$ 13,934	$ 14,538
Leasehold improvements	18,466	18,467
Furniture and fixtures	1,067	1,086
Office equipment	281	324
Computer equipment and software	1,770	1,685
Transportation equipment	46	46
Total property and equipment	35,564	36,146
Less: Accumulated depreciation and amortization	(24,340)	(21,279)
Property and equipment, net	$ 11,224	$ 14,867

All property and equipment are maintained in the United States. Depreciation expense was $1.2 million and $1.3 million for the three months ended September 30, 2026 and 2025, respectively, and $3.8 million and $3.9 million for the nine months ended September 30, 2026 and 2025, respectively.

5. Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued clinical and preclinical study costs	$ 16,395	$ 10,273
Payroll and related expenses	11,712	13,806
Consulting and outside services	6,978	2,666
Other accrued expenses	126	129
Total accrued and other current liabilities	$ 35,211	$ 26,874

6. Research and Collaboration Arrangements

Collaboration and license revenue for each period was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Otsuka Pharmaceutical Co., Ltd.	$ 4,055	$ —	$ 10,704	$ —
Cystic Fibrosis Foundation	90	90	270	119
Total revenue	$ 4,145	$ 90	$ 10,974	$ 119

Deferred revenue is summarized as follows (in thousands):

	September 30, 2026	December 31, 2025
Otsuka Pharmaceutical Co., Ltd.	$ 2,355	$ —
Cystic Fibrosis Foundation	835	1,105
Total deferred revenue	$ 3,190	$ 1,105

Cystic Fibrosis Foundation (“CFF”)

In September 2016, the Company entered into an award agreement for the Optimized Adeno-Associated Virus for Lung Epithelia Gene Delivery Development Program with CFF, a non-profit organization dedicated to finding a cure for cystic fibrosis, an inherited disorder that causes disease in the pulmonary airways leading to morbidity and mortality. Under this agreement, CFF contributes funding to help advance the Company’s cystic fibrosis research program. The September 2016 grant award agreement was incorporated into a new grant award agreement with CFF in September 2017 with the same objectives, which was subsequently amended in August 2018 and February 2021. In August 2023, the Company executed a third amendment to the agreement (the “August 2023 Amendment”), which modified the research plan, increased the aggregate milestone payments from $3.5 million to $6.3 million and extended the estimated project completion date. The aforementioned September 2017 agreement and three amendments are collectively referred to as the “CFF Agreement”. The August 2023 Amendment represents a contract modification to an existing contract under ASC Topic 606, given the amendment did not include any additional goods or services, and the remaining research activities are not distinct from those previously provided. The August 2023 Amendment did not impact the transaction price, given the increased award amount relates to variable consideration for future milestones that are fully constrained. Accordingly, the contract modification did not result in a revenue adjustment. As of September 30, 2026 and December 31, 2025, the Company had achieved cumulative milestones totaling $1.8 million under the CFF Agreement. The remaining award amount will be paid by CFF based on achievement of certain development milestones by the Company.

The Company expects to make payments to CFF equal to six times the actual award received by the Company in three installments within the first four years of the first commercial sale of a product developed under this agreement. The Company also has agreed to make future sales-based milestone payments to CFF of up to three times the actual award received upon achieving specified commercialization milestones with respect to the first of any product developed utilizing any compound covered under the CFF Agreement. The CFF Agreement also requires the Company to pay to CFF royalties of a mid-single digit percentage, up to six times the actual award received, on any amounts received by the Company from the sale, license or transfer to a third-party of rights in the technology developed as a result of this collaboration. Any such royalty payments shall be credited against the payments owed by the Company upon first commercial sale. In the event of a change of control of the Company, CFF will receive certain payments, depending on the timing of the change of control and the size of the transaction.

To date, the Company has not developed a commercial product in connection with the CFF Agreement, and it has not licensed, sold or otherwise transferred to another party the product developed under the CFF Agreement or the underlying technology.

If at any time prior to the first commercial sale of a product developed as a result of the CFF Agreement, the Company ceases to use commercially reasonable efforts to develop or commercialize any product under the CFF Agreement for a continuous period of 180 consecutive days and fails to present a reasonable plan to resume commercially reasonable efforts, the Company will grant to CFF an irrevocable, exclusive worldwide interruption license under all of the Company's interest in the research plan technology to exploit such product. Any third-party license granted by the Company shall be subject to such interruption license.

The Company identified one performance obligation within the CFF Agreement for research activities. The CFF Agreement does not include a significant financing component.

The Company concluded that the transaction price should not include the variable consideration related to future research milestones as they were considered to be constrained as it is probable that the inclusion of such variable consideration could result in a significant reversal of cumulative revenue in the future. The Company re-evaluates the transaction price and estimated period of performance at each reporting period.

Revenue recognized during the three and nine months ended September 30, 2026 was $0.1 million and $0.3 million, respectively, while revenue recognized during each of the three and nine months ended September 30, 2025 was $0.1 million. As of September 30, 2026 and December 31, 2025, deferred revenue relating to the CFF Agreement was $0.8 million and $1.1 million, respectively. There were no accounts receivable from CFF under the CFF Agreement as of September 30, 2026 and December 31, 2025. As of September 30, 2026 and December 31, 2025, the aggregate amount of the transaction price allocated to the remaining performance obligation was $0.8 million and $1.1 million, respectively. Based on current timelines, the deferred revenue is expected to be recognized as revenue over the next four years as the Company performs research services through the completion of IND-enabling studies.

The obligation to make payments to CFF upon a change of control meets the definition of an embedded derivative that is required to be bifurcated and separately accounted for as a derivative liability. See Note 3, Fair Value Measurements and Marketable Securities, and Note 16, Derivative Liability, for further discussion of the embedded derivative.

Otsuka Pharmaceutical Co., Ltd.

On October 31, 2025, the Company entered into a Collaboration and License Agreement (the "Otsuka Agreement") with Otsuka. Pursuant to the Otsuka Agreement, the Company granted Otsuka an exclusive royalty-bearing sublicensable license to its intellectual property to develop, manufacture and commercialize 4D-150, its lead product candidate for ophthalmological diseases, in Japan, Korea, China, Australia, and certain other Asia-Pacific markets ("Otsuka Territory"). The Company retains full development and commercialization rights for 4D-150 outside the Otsuka Territory, including the United States, Latin America, and Europe.

Otsuka will lead all regulatory and commercialization activities in the Otsuka Territory. The Company will lead all Phase 3 clinical activity globally, including within the Otsuka Territory. In aggregate, the Company is currently responsible for separate global phase 3 trials for wet age-related macular degeneration ("wet AMD") and diabetic macular edema (“DME”), local clinical trials in the Otsuka Territory as required by local regulatory authorities, and several other studies, including the related regulatory activities and long-term follow-up studies. The Company and Otsuka will coordinate and review the development and other activities through a joint steering committee.

The Company also will manufacture and supply 4D-150 to Otsuka for clinical and commercial use at a supply price derived from the Company's manufacturing costs plus a margin.

The Company has received a nonrefundable upfront cash payment of $85.0 million and is eligible to receive quarterly clinical trial cost sharing and reimbursement amounts. In addition, the Company is eligible for up to $335.5 million in potential regulatory and commercial milestone payments and tiered double-digit royalties on net sales in the Otsuka Territory, and subject to royalty reductions under certain circumstances.

The Otsuka Agreement will remain in effect, unless earlier terminated, on a country-by-country basis, until the date that Otsuka is no longer developing or commercializing 4D-150 in such country within the Otsuka Territory. Otsuka may terminate the Otsuka Agreement for convenience, on a country-by-country basis, upon sufficient prior written notice as per the Otsuka Agreement, or due to safety reasons or the failure of certain of the Company’s related clinical trials to achieve their primary endpoints. The Company may terminate the Otsuka Agreement upon notice if Otsuka ceases all development activities and commercialization of 4D-150 in Japan for an agreed upon period as per the Otsuka Agreement and does not resume such activities or commercialization within a specified notice period. Upon termination, any license granted by the Company to Otsuka will terminate.

The Company concluded that Otsuka is a customer and that the arrangement represents a contract with a customer under the scope of ASC 606. The Company identified the following promised goods and services that represent performance obligations:

- the exclusive license to its intellectual property to develop, manufacture and commercialize 4D-150 in the Otsuka Territory,
- performance of separate global phase 3 trials for wet AMD and DME, local clinical trials in the Otsuka Territory as required by the local regulatory authorities, and several other studies, including the associated regulatory and joint steering committee activities. Separate performance obligations were identified for each individual trial or study.

The license was considered functional intellectual property as of the inception of the Otsuka Agreement and distinct from other promises under the contract, as Otsuka can benefit from the license on its own or together with other readily available resources. Each of the clinical trial and other study services were considered distinct as the customer can benefit from these services together with the license transferred at the inception of the Otsuka Agreement. The clinical trial and other study services will not modify or customize the initial intellectual property transferred at contract inception due to the late stage of development of the intellectual property.

The Company concluded manufacturing and supply of 4D-150 for clinical and commercial use does not represent a performance obligation, as these activities are at Otsuka's option. Product supply is priced at standalone selling prices, and therefore does not provide Otsuka with material rights.

To the extent Otsuka requests the Company to supply 4D-150, such supply will be considered a separate contract with the customer.

The initial transaction price includes the upfront cash payment and variable consideration for clinical trials and other studies performance obligations, some of which have started and others that have not yet started as of September 30, 2026. The upfront cash payment is $85 million and was received during the year ended December 31, 2025. The variable consideration in the form of the estimated cost sharing and reimbursement of approximately $29.3 million represents the amount allocated to unsatisfied or partially unsatisfied performance obligations, that have already started as of September 30, 2026, and was allocated entirely to the clinical trials and other studies performance obligations using the variable consideration allocation exception.

The regulatory milestone amounts are not currently probable and have not been included in the transaction price as the amounts are fully constrained. The sales-based commercial milestones and royalties relate to the granted intellectual property license and will be recognized when the related sales occur.

At the end of each reporting period, the Company will re-evaluate the estimated variable consideration and if necessary, adjust the transaction price.

To determine the standalone selling prices of each performance obligation, the Company used significant estimates and assumptions that include but are not limited to, expected market opportunity and pricing, expected future costs of clinical trials and other studies, and timelines and likelihood of success of clinical and regulatory activities. For the standalone selling price of the license, the Company used a discounted cash flow analysis of projected cash flows and potential revenues from the commercial sales of 4D-150 in the Otsuka Territory. To determine the standalone selling prices of the Company's obligations to conduct clinical trials and other studies, the expected cost plus margin approach was used.

Variable consideration to which the Company is entitled is allocated directly to the associated performance obligations, as it is triggered by the Company's performance or represents specific outcomes from such performance, and the resulting allocation meets the allocation objective.

The upfront amount of $85.0 million was allocated entirely to the license performance obligation and was recognized at a point in time upon the transfer of control during the year ended December 31, 2025.

Revenue attributable to the remaining performance obligations to conduct clinical trials and other studies will be recognized over time as the underlying services are performed, over the period through the completion of program development activities. Progress is measured using an input method based on cumulative cost incurred relative to the total estimated cost of the performance obligation. Estimated progress and the underlying costs will be reviewed and adjusted as necessary at every reporting date. Revenue from clinical trials and other studies performance obligations was approximately $4.1 million and $10.7 million during the three and nine months ended September 30, 2026, respectively.

The transaction price amount allocated to unsatisfied or partially unsatisfied performance obligations as of September 30, 2026 was approximately $29.3 million, expected to be recognized during 2026 through 2032 as clinical trials and other studies continue. Certain performance obligations have not started as of September 30, 2026 and the related amounts are not included above.

The amount due from Otsuka was $4.0 million as of September 30, 2026, for the estimated cost sharing and reimbursement and is presented as collaboration receivable on the Company's condensed balance sheets.

7. License Arrangements

Aevitas Therapeutics, Inc. and The Trustees of the University of Pennsylvania

On April 21, 2023, the Company entered into an agreement (the "Aevitas Agreement") with Aevitas Therapeutics, Inc. ("Aevitas"), pursuant to which the Company acquired all of Aevitas' worldwide rights to short-form human complement factor H ("sCFH"), which the Company plans to use for its 4D-175 product candidate research program. The asset purchase was accounted for as an asset acquisition. As consideration for the Aevitas Agreement, the Company shall pay Aevitas up to approximately $144.1 million in cash upon certain late-stage milestones being achieved, including $7.2 million for development milestones, $68.0 million for regulatory milestones and $68.9 million for sales milestones plus royalties in the low single digits range on sales of 4D-175. In addition, as part of the Aevitas Agreement, the Company was assigned a License Agreement for sCFH with the Trustees of the University of Pennsylvania, under which the Company shall pay the University of Pennsylvania up to approximately $41.6 million in cash upon certain late-stage milestones being achieved, including $1.9 million development, $21.5 million regulatory and $18.2 million sales milestones plus royalties in the low single digits range on sales of 4D-175. No upfront consideration was paid under the Aevitas Agreement.

As of September 30, 2026, the Company has not recorded a liability related to contingent consideration for future milestone and royalty payments to either Aevitas or the University of Pennsylvania, as the achievement of such milestones has not occurred and was not deemed probable and product sales have not commenced.

Regents of the University of California

The Company has exclusive, worldwide license agreements (the "UC Agreements") with the Regents of the University of California (the "UC Regents") relating to the use of certain patents and intellectual property surrounding its core technologies, including Therapeutic Vector Evolution. Pursuant to each of the UC Agreements executed prior to January 2019, the Company was obligated to pay a (i) non-refundable license fee of $5,000 upon execution, (ii) a non-refundable license fee of $5,000 each year thereafter, until sales of a licensed product are made and royalties are paid to the UC Regents, (iii) reimbursement of domestic and foreign patent filing, prosecution and maintenance fees, and (iv) either $50,000 or issuance of a 3% equity interest in the Company upon the closing of the first qualified financing at the option of the UC Regents. The Company's first qualified financing occurred in 2015 and at the election of the UC Regents, the Company issued the UC Regents in January 2016 an amount of common stock equal to 6% of the equity interests in the Company pursuant to the applicable clause in each of the UC Agreements.

Pursuant to an agreement with the UC Regents executed in January 2019 the Company paid a non-refundable license fee of $50,000 to the UC Regents upon execution of the agreement. The Company is obligated to pay a non-refundable license fee of $5,000 on the one-year anniversary of the contract effective date and each year thereafter, until sales of a licensed product are made and royalties are paid to the UC Regents.

In addition, the Company is obligated to make certain contingent payments including (i) development milestones up to $3.1 million, (ii) low single digit royalties on the net sales of its developed products that consist of a minimum annual royalty of up to $0.1 million per year for the term of the agreement beginning in the first calendar year after the year in which net sales first occurred, and (iii) sublicense consideration in the mid-teens to the mid-twenties-range on any future sublicensing arrangements the Company may enter into with third-party licensees.

As of September 30, 2026, the Company has not recorded a liability related to contingent consideration for future milestone and royalty payments to UC Regents, as the achievement of such milestones has not occurred and was not deemed probable and product sales have not commenced.

8. Commitments and Contingencies

Operating Lease Commitments

5980 Horton Street Building Lease

In May 2015, the Company executed a lease agreement (the "5980 Horton Lease") for office and laboratory space in Emeryville, California. The 5980 Horton Lease, as amended, expired in August 2026. As of September 30, 2026, the right-of-use asset and lease liability related to the 5980 Horton Lease were both zero. As of December 31, 2025, the right-of-use asset and lease liability related to the 5980 Horton Lease were $0.3 million and $0.4 million, respectively.

5858 Horton Street Lease and Expansion

In October 2018, the Company executed a lease agreement (the "5858 Horton Lease") for office and laboratory facilities in Emeryville, California. The 5858 Horton Lease, as amended in 2019, 2021 and 2022, consists of approximately 40,802 square feet of space and has a lease term through December 31, 2029. In July 2024, the Company extended the term of the 5858 Horton Lease for a period of twelve months to December 31, 2030. In accordance with ASC Topic 842, *Leases*, the Company accounted for the extension as a modification and remeasured the lease liability based on the new lease term and an updated, estimated incremental borrowing rate of 10.75%. The modification resulted in an increase to the lease liability of $0.8 million and a corresponding increase to the carrying value of the right-of-use asset. No gain or loss was recognized upon the modification. As of September 30, 2026, the right-of-use asset and lease liability related to the 5858 Horton Lease were $7.8 million and $10.0 million, respectively. As of December 31, 2025, the right-of-use asset and lease liability related to the 5858 Horton Lease were $8.8 million and $11.2 million, respectively.

In July 2024, the Company also entered into a lease agreement for additional office and laboratory space in Emeryville, California (the "5858 Horton Expansion Lease"). The 5858 Horton Expansion Lease consists of approximately 32,038 square feet of space and commenced on September 1, 2024 and has a lease term through December 31, 2030. As of September 30, 2026, the right-of-use asset and lease liability related to the 5858 Horton Expansion Lease were $6.9 million and $7.7 million, respectively. As of December 31, 2025, the right-of-use asset and lease liability related to the 5858 Horton Expansion Lease were $7.8 million and $8.6 million, respectively. The discount rate used to measure the lease liability was 11.02%.

Emeryville Warehouse Lease

In January 2024, the Company entered into a lease agreement for warehouse space in Emeryville, California (the "Warehouse Lease"). The Warehouse Lease commenced on August 1, 2024. The Warehouse Lease consists of approximately 7,800 square feet of warehouse space and has a lease term through December 31, 2029. As of September 30, 2026, the right-of-use asset and lease liability related to the Warehouse Lease were $1.0 million and $1.1 million, respectively. As of December 31, 2025, the right-of-use asset and lease liability related to the Warehouse Lease were each $1.2 million. The discount rate used to measure the lease liability related to the Warehouse Lease was 10.69%.

The following table summarizes the components of lease expense, which are included in operating expenses in the Company's condensed statements of operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating lease cost	$ 1,302	$ 1,343	$ 3,990	$ 4,031
Variable lease cost	670	672	2,024	2,094
Total	$ 1,972	$ 2,015	$ 6,014	$ 6,125

Variable lease payments include amounts relating to common area maintenance and are recognized in the condensed statements of operations as incurred.

Cash paid for amounts included in the measurement of the Company's operating lease liabilities and presented within cash used in operating activities in the condensed statements of cash flows was $4.3 million and $4.2 million for the nine months ended September 30, 2026 and 2025, respectively.

The following table summarizes supplemental information related to operating leases:

	September 30, 2026	December 31, 2025
Weighted-average remaining lease term (in years):	4.2	4.8
Weighted-average discount rate:	10.9%	10.8%

The following table summarizes the maturities of lease liabilities as of September 30, 2026 (in thousands):

2026 (remaining three months)	$ 1,318
2027	5,350
2028	5,510
2029	5,675
2030	5,456
Total future minimum lease payments	23,309
Less: Amount representing interest	(4,575)
Present value of future minimum lease payments	18,734
Less: Current portion of operating lease liabilities	(5,310)
Long-term portion of operating lease liabilities	$ 13,424

Indemnification Agreements

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions, such as with vendors and other parties. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently maintains directors' and officers' liability insurance that would generally enable it to recover a portion of any future amounts paid. The Company believes the estimated fair value of its indemnification agreements in excess of applicable insurance coverage is not material.

Contractual Obligations and Commitments

The Company enters into various agreements in the ordinary course of business, such as those with suppliers, CROs, CDMOs and clinical trial sites. These contracts generally provide for termination on notice or may have a potential termination fee if a purchase order is canceled within a specified time. The total value of non-cancellable obligations under contracts was $4.3 million and $4.0 million as of September 30, 2026 and December 31, 2025, respectively. This presentation of non-cancellable purchase obligations does not include any estimates of potential reduction of such liabilities related to mitigation obligations of the counterparties in the event of cancellation under the terms of the Company's engagements.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of its business. If applicable, the Company records a legal liability when it believes that it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount. There are no material legal proceedings outstanding at September 30, 2026.

9. Long-Term Debt

In June 2026, the Company entered into a Loan and Security Agreement (the “Loan and Security Agreement”) with Hercules Capital, Inc., providing for up to $200.0 million in term loan borrowings. At the closing on June 24, 2026, the Company had access to a $50.0 million tranche, of which it borrowed $20.0 million. The remaining $30.0 million is available, at the Company's option, through June 15, 2027. The Company may draw up to an additional $100.0 million in three separate tranches upon achievement of certain clinical, regulatory, financing and capitalization milestones. As of September 30, 2026, the Company had not met the requirements to access the funds under these tranches, as it had not achieved the related milestones. An additional fifth tranche of $50.0 million may be made available upon the Company's request and at Hercules’ sole discretion and is not contingent upon the Company’s achievement of the milestones applicable to the prior tranches. The Loan and Security Agreement matures on June 1, 2031. The initial borrowing of $20.0 million bears interest at a floating rate equal to the greater of (i) the prime rate plus 2.0% and (ii) 8.75%, and all future borrowings, including the available balance of $30.0 million of the $50.0 million tranche available as of June 24, 2026, bear interest at a floating rate equal to the greater of (i) the prime rate plus 2.5% and (ii) 9.25%. The floating interest rate is capped at 0.75% more than the interest rate at the time of the borrowing. The Company is required to make monthly interest-only payments for borrowings under the initial tranche of $50.0 million for a period of 29 months, which may be extended by up to an additional 30 months upon achievement of certain clinical, regulatory, financing and capitalization milestones.

The Loan and Security Agreement includes an end-of-term charge ranging from 3.70% to 6.50% of the aggregate principal amount, depending on the timing of the repayment. The recognition of the end-of-term charge is reflected as interest expense over the term of the borrowing using the effective interest rate method. The Company may voluntarily prepay outstanding borrowings, subject to prepayment premiums ranging from 1.0% to 3.0% of the principal amount prepaid, depending on the timing of repayment.

In connection with the Loan and Security Agreement, the Company paid a $0.5 million facility fee for the $50.0 million tranche and is subject to a 1.00% facility fee for subsequent borrowings. Because the facility fee relates to the total $50.0 million initial tranche, the Company allocated the costs among the two initial borrowing tranches based on the relative borrowing capacity available under each tranche. In addition to the initial facility fee, the Company incurred approximately $2.1 million of debt issuance costs, consisting primarily of lender fees and third-party legal and other transaction costs. Because the debt issuance costs relate to the $150.0 million for the first four tranches of the Loan and Security Agreement, the Company allocated the costs among the various borrowing tranches based on the relative borrowing capacity available under each tranche. Facility fees and debt issuance costs attributable to funded borrowings were recorded as a reduction to the carrying value of the debt and are being amortized to interest expense using the effective interest method over the expected term of the borrowing. Facility fees and debt issuance costs attributable to unfunded borrowing commitments were capitalized to prepaid and other current assets or other non-current assets according to the access period or classification of the underlying debt, as appropriate, and are being amortized to interest expense over the applicable commitment periods or will be reclassified as debt upon funding of the related borrowings.

The Loan and Security Agreement contains financial covenants, including minimum cash and performance-based covenants, that are not yet subject to testing or effective as of September 30, 2026. Upon the occurrence of certain events and beginning no earlier than January 1, 2028, the Company may become subject to minimum cash and performance-based financial covenants. The Loan and Security Agreement contains customary events of default, including failure to make required payments or maintain compliance with covenants, breach, default, insolvency, attachment or judgment events and any circumstance which could reasonably be expected to have a material adverse effect on the Company. The Loan and Security Agreement also contains customary affirmative and restrictive covenants, representations and warranties associated with a secured loan facility, including certain limitations on indebtedness, liens, investments, distributions, mergers or acquisitions and corporate changes.

As of September 30, 2026, the outstanding principal under the Loan and Security Agreement was $20.0 million, bearing interest at a rate of 9.00% per annum, with an effective interest rate of 10.9%.

The future principal payments due under the Loan and Security Agreement as of September 30, 2026 were as follows (in thousands):

Remainder of 2026	$	—
2027		—
2028		575
2029		7,231
2030		7,919
Thereafter		5,575
Total	$	21,300

As of September 30, 2026, the carrying value of the Loan and Security Agreement was as follows (in thousands):

Principal outstanding	$	20,000
Less: unamortized discount and debt issuance costs		(321)
Long-term debt, net	$	19,679

As of September 30, 2026, debt issuance costs and debt discount of approximately $2.0 million were included in prepaid expenses and other current assets and in other non-current assets on the condensed balance sheet, as appropriate. For the three and nine months ended September 30, 2026, the Company recognized interest expense of $0.5 million and $0.6 million, respectively, for borrowings under the Loan and Security Agreement. The Loan and Security Agreement is secured by a first-priority security interest in substantially all of the Company's assets, including intellectual property, subject to customary exclusions.

10. Income Taxes

For the three and nine months ended September 30, 2026 and 2025, the Company did not record a federal or state income tax provision due to its recurring net losses. In addition, the Company has taken a full valuation allowance against its net deferred tax assets as the Company believes it is not more likely than not that the benefit will be realized.

11. Common Stock

As of September 30, 2026 and December 31, 2025, the Company's certificate of incorporation authorized the Company to issue 300,000,000 shares of common stock, at the par value of $0.0001 per share. The holder of each share of common stock is entitled to one vote per share.

Common stockholders are entitled to dividends, if and when declared by the board of directors. To date, no dividends on common stock have been declared by the board of directors.

The Company has reserved common stock, on an as-converted basis, for future issuance as follows:

	September 30, 2026	December 31, 2025
Exercise of pre-funded warrants	16,004,945	10,335,665
Exercise of stock options issued and outstanding and future vesting of restricted stock units	13,389,300	10,157,578
Issuance of common stock under the 2020 Equity Incentive Award Plan and 2025 Employment Inducement Award Plan	2,519,067	2,506,434
Issuance of common stock under the 2020 Employee Stock Purchase Plan	390,372	182,775
Exercise of common stock warrants	30,000	30,000
Total common stock reserved for future issuance	32,333,684	23,212,452

Funding Agreement with CFF — In April 2020, CFF made a $10.0 million investment in the Company's Series C redeemable convertible preferred stock financing. In return for the investment, CFF received shares of Series C redeemable convertible preferred stock, and the Company and CFF entered into a Funding Agreement (the "Funding Agreement"). Pursuant to the terms of the Funding Agreement, except in the event of a technical failure, the $10.0 million received from CFF will be used to advance the development program for 4D-710, the Company's lead product candidate in cystic fibrosis, or any other therapeutic approved by the Program Advisory Group ("PAG") to alleviate pulmonary complications of cystic fibrosis (the "Funding Agreement Product").

CFF committed to provide an additional $4.0 million of funding upon acceptance of an IND application or its equivalent to allow for human testing of the Funding Agreement Product ("Acceptance").

In October 2021, the IND was cleared by the U.S. Food and Drug Administration and CFF made the additional investment of $4.0 million in cash for the issuance of 125,715 shares of the Company's common stock to CFF.

The Company was committed to providing an amount equal to the funding provided by CFF to be used solely to advance the Funding Agreement Product. As of June 30, 2023, the funding commitment has been fulfilled. Under the terms of the Funding Agreement, neither the $10.0 million investment in the Series C redeemable convertible preferred stock, which converted to common stock as of December 31, 2020, nor the $4.0 million of funding upon Acceptance are restricted as to withdrawal or usage.

CFF purchased 776,398 shares of the Company's common stock for $7.5 million in October 2025. The Company will use the proceeds of this investment to support continued development of 4D-710. The Company also agreed with CFF to form a Joint Steering Committee, with senior clinical development and regulatory expertise to enhance strategic planning, guidance, and coordination of 4D-710's development. This agreement between CFF and the Company entered into in October 2025 also provides that CFF will invest an additional $3.6 million in exchange for shares of the Company's common stock subject to achievement of specific clinical milestones and at the option of the Company. This agreement between the Company and CFF entered into in October 2025 does not modify the prior agreements with CFF.

Sales Agreement with Leerink Partners LLC ("Leerink") — In June 2024, the Company entered into a Sales Agreement (the "Leerink Sales Agreement") with Leerink as sales agent to sell shares of the Company's common stock, from time to time, with aggregate gross sales proceeds of up to $250.0 million pursuant to a Registration Statement on Form S-3 that the Company filed with the SEC in February 2024, and subsequently amended in February 2025, as an "at-the-market" offering under the Securities Act. For the year ended December 31, 2025, 1,175,000 shares of the Company's common stock were sold pursuant to the Leerink Sales Agreement for net proceeds to the Company of $9.6 million, after deducting issuance costs. For the nine months ended September 30, 2026, 3,518,472 shares were sold pursuant to the Leerink Sales Agreement for net proceeds to the Company of $31.6 million, after deducting issuance costs.

12. Stock-based Compensation

2025 Employment Inducement Award Plan

On February 3, 2025, the Company's board of directors adopted the 2025 Employment Inducement Plan (the "Inducement Plan") pursuant to which the Company reserved 500,000 shares of its common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors, as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Marketplace Rules of the Nasdaq Stock Market. The Inducement Plan provides for the grant of stock options, restricted stock units, and other stock-based awards. In January 2026, the Company's board of directors adopted an amendment to the Inducement Plan to reserve an additional 1,000,000 shares of common stock under the Inducement Plan. As of September 30, 2026, there were 752,550 shares available for future grants under the Inducement Plan.

2020 Incentive Award Plan

In December 2020, the Company adopted the 2020 Incentive Award Plan ("2020 Plan"), which became effective on December 10, 2020. The 2020 Plan initially reserved 2,606,546 shares of common stock for the issuance of stock options, stock appreciation rights, restricted stock awards, restricted stock units, performance bonus awards, performance stock units, dividend equivalents or other stock or cash based award granted to employees, directors and consultants of the Company. The number of shares reserved for future issuance under the 2020 Plan will increase annually on the first day of each fiscal year beginning in 2021 and ending in 2030 by the lesser of (i) 5% of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such number of shares of common stock as determined by the Company's board of directors, provided, however, no more than 18,000,000 shares of the Company's common stock may be issued upon the exercise of incentive stock options. As a result of the operation of the automatic annual increase provision of the 2020 Plan, an additional 2,289,625 shares of common stock became available for issuance on February 28, 2025 and an additional 2,880,394 shares of common stock became available for issuance on March 18, 2026 under the 2020 Plan. All stock options are exercisable over a period not to exceed the contractual term of ten years from the date the stock options were issued. As of September 30, 2026, there were 1,766,517 shares available for grant under the 2020 Plan.

Following the effectiveness of the 2020 Plan, the Company will not make any further grants under the 2015 Equity Incentive Plan (the "2015 Plan"). However, the 2015 Plan continues to govern the terms of stock options that remain outstanding under the 2015 Plan.

2015 Equity Incentive Plan

The 2015 Plan provided for grants of stock options, stock appreciation rights, restricted stock and restricted stock unit awards to employees, directors and consultants of the Company. As of September 30, 2026, stock options to purchase 1,090,890 shares of common stock were outstanding under the 2015 Plan. All stock options are exercisable over a period not to exceed the contractual term of ten years from the date the stock options were issued and are granted at prices not less than the estimated fair market value of the Company's common stock on the grant date as determined by the board of directors.

No additional grants will be made under the 2015 Plan, and all outstanding grants under the 2015 Plan that are repurchased, forfeited, expire or are cancelled are returned to the 2015 Plan and are not available for grant under the 2020 Plan.

Employee Stock Purchase Plan

In December 2020, the Company adopted the 2020 Employee Stock Purchase Plan (the "2020 ESPP"). Under the 2020 ESPP, 252,337 shares of the Company's common stock were initially reserved for employee purchases of the Company's common stock under terms and provisions established by the Company's board of directors and approved by the Company's stockholders. The number of shares reserved for future issuance under the 2020 ESPP will increase annually on the first day of each fiscal year beginning in 2021 and ending in 2030 by the lesser of (i) 1% of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such number of shares of common stock as determined by the Company's board of directors, provided, however, no more than 15,000,000 shares of the Company's common stock may be issued under the 2020 ESPP. As a result of the operation of this annual increase provision of the 2020 ESPP, an additional 150,000 shares of common stock became available on February 28, 2025 and an additional 576,079 shares of common stock became available for issuance on March 18, 2026 under the 2020 ESPP.

Under the 2020 ESPP, the Company's employees may purchase common stock through payroll deductions at a price equal to 85% of the lower of the fair market value of the stock at the beginning of the offering period or at the end of each applicable purchase period. The 2020 ESPP provides for a series of overlapping 24-month offering periods comprising four six-month purchase periods. Contributions under the 2020 ESPP are limited to a maximum of 15% of an employee's eligible compensation.

Restricted Stock Units

The Company has granted restricted stock unit (RSU) awards under the 2020 Incentive Award Plan that vest over a period of four years. The following table summarizes the RSU activity:

	Number of Shares
Unvested balance at December 31, 2025	744,770
Awarded	1,463,576
Vested	(218,291)
Canceled/Forfeited	(190,373)
Unvested balance at September 30, 2026	1,799,682

Stock Options

The following table summarizes the stock options activity:

	Number of Shares Underlying Outstanding Options
Balances at December 31, 2025	9,412,808
Options granted	3,276,795
Options exercised	(330,688)
Options expired	(422,605)
Options forfeited	(346,692)
Balances at September 30, 2026	11,589,618
Options exercisable at September 30, 2026	6,411,199
Options vested and expected to vest at September 30, 2026	11,589,618

The Company estimates the fair value of stock options using the Black-Scholes option pricing model. The fair value of employee and nonemployee stock options is recognized on a straight-line basis over the requisite service period of the awards. The fair value of the Company's stock options was estimated using the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Expected term	6.0 - 6.1 years	6.0 - 6.1 years	5.9 - 6.1 years	5.9 - 6.1 years
Expected volatility	86.3% - 86.4%	88.6% - 89.8%	85.9% - 89.0%	84.9% - 89.8%
Risk-free interest rate	4.2% - 4.6%	3.7% - 4.1%	3.8% - 4.6%	3.7% - 4.6%
Expected dividend yield	—%	—%	—%	—%

Expected Term. The expected term for employee stock options is calculated using the simplified method as the Company does not have sufficient historical information to provide a basis for this estimate. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. The expected term for nonemployee stock options is the contractual term of the stock options.

Expected Volatility. The expected volatility is based on a mix of the Company's historical volatility and the historical volatility of comparable companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. For each grant, the Company measured historical volatility over a period equivalent to the expected term.

Risk-free Interest Rate. The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues whose term is similar in duration to the expected term of the respective stock option.

Expected Dividend Yield. The Company has not paid and does not anticipate paying any dividends on its common stock in the future. Accordingly, the Company has estimated the dividend yield to be zero percent.

Stock-Based Compensation Expense

The following table is a summary of stock-based compensation expense incurred for employees and nonemployees by function (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 2,388	$ 2,184	$ 6,734	$ 8,663
General and administrative	5,869	2,335	11,860	7,800
Total stock-based compensation expense	$ 8,257	$ 4,519	$ 18,594	$ 16,463

13. Common Stock Warrants

In May 2018, the Company issued a warrant for 23,669 shares of the Company's common stock to a service provider with an exercise price of $3.19 per share. The fair value of the warrant was determined at the issuance date using the Black-Scholes option pricing model. The warrant was fully vested upon issuance and was exercised in May 2025 through a cashless exchange under the terms of the original agreement.

In December 2020, the Company issued a warrant for 30,000 shares of the Company's common stock to a service provider with an exercise price of $18.00 per share. This warrant vests over a period of four years and expires in 2027. The fair value of the warrant was determined at the issuance date using the Black-Scholes option pricing model.

The Company recognized no expense related to the above warrant shares during the three and nine months ended September 30, 2026 and 2025.

14. Pre-funded Warrants

In February 2024, the Company completed an underwritten public follow-on offering which included the sale of pre-funded warrants to purchase 3,583,476 shares of the Company's common stock at an offering price of $29.4999 per underlying share (the "February 2024 Warrants"). The Company valued the February 2024 Warrants at issuance and recorded net proceeds of $99.4 million, after deducting underwriters' fees, during the year ended December 31, 2024 related to the sale of the February 2024 Warrants. In February 2025, two holders of the February 2024 Warrants gave notice of exercise and the Company issued 508,465 shares of common stock in a cashless exchange under the terms of the February 2024 Warrants.

In November and December 2024, the Company entered into exchange agreements (the "2024 Exchange Agreements") with each of Biotechnology Value Fund, L.P. and certain of its affiliates (collectively, "BVF") and RA Capital Healthcare Fund, L.P. ("RA Capital"), respectively. Pursuant to the 2024 Exchange Agreements, BVF and RA Capital exchanged 5,775,000 and 535,000 shares, respectively, of the Company's common stock for pre-funded warrants to acquire the same respective number of shares of the Company's common stock (the "2024 Exchange Warrants"). The fair value of the common stock exchanged approximated the fair value of the pre-funded warrants issued as of the transaction dates and no net proceeds were recorded in connection with the transactions. On December 22, 2025, BVF gave notice of exercise and the Company issued 178,280 shares of the Company's common stock in a cashless exchange under the terms of the 2024 Exchange Warrants.

In November 2025, the Company completed the 2025 Offering which included the sale of pre-funded warrants to purchase 1,128,949 shares of the Company's common stock at an offering price of $10.5099 per underlying share (the "November 2025 Warrants"). The Company valued the November 2025 Warrants at issuance and recorded net proceeds of $11.2 million, after deducting underwriters' fees, during the year ended December 31, 2025.

On January 22, 2026, the Company entered into exchange agreements with RA Capital and BVF, pursuant to which RA Capital and BVF exchanged 4,850,000 and 1,750,000 shares, respectively, of the Company's common stock for pre-funded warrants to acquire the same respective number of shares of the Company's common stock (together with the February 2024 Warrants, the 2024 Exchange Warrants, the November 2025 Warrants, collectively, the "Pre-funded Warrants"). The fair value of the common stock exchanged approximated the fair value of the pre-funded warrants issued as of the transaction dates and no net proceeds were recorded in connection with the transactions. As of September 30, 2026, 16,004,945 Pre-funded Warrants were outstanding.

On September 30, 2026, BVF gave notice of exercise and the Company issued 930,712 shares of the Company's common stock in a cashless exercise under the terms of the 2024 Exchange Warrants.

The Pre-funded Warrants each have an exercise price of $0.0001 per underlying share of common stock, are exercisable at any time until they are fully exercised and will not expire until they are fully exercised. The Pre-funded Warrants are classified as a component of stockholders' equity within additional paid-in-capital. The number of shares of the Company's common stock issuable upon exercise of each Pre-funded Warrant is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting shares of the Company's common stock, as well as upon any distribution of assets, including cash, stock or other property, to the Company's stockholders.

15. Net Loss Per Share, Basic and Diluted

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator				
Net loss	$ (78,056)	$ (56,876)	$ (219,751)	$ (159,506)
Denominator				
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	72,251,127	56,126,330	70,211,785	55,933,890
Net loss per share, basic and diluted	$ (1.08)	$ (1.01)	$ (3.13)	$ (2.85)

The Company has issued and sold Pre-funded Warrants to purchase shares of common stock of the Company at a nominal exercise price of $0.0001 (see Note 14, Pre-funded Warrants). The shares of common stock into which the Pre-funded Warrants may be exercised are considered outstanding for the purposes of computing earnings per share, because the shares may be issued for little or no consideration, they are fully vested and the Pre-funded Warrants are immediately exercisable upon their issuance date.

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	September 30,	
	2026	2025
Stock options issued and outstanding	11,589,618	9,681,984
Restricted stock units subject to future vesting	1,799,682	698,019
2020 ESPP	303,189	384,562
Common stock warrants	30,000	30,000
Total	13,722,489	10,794,565

16. Derivative Liability

The Company identified an embedded derivative resulting from the change of control provision in the CFF Agreement. Embedded derivatives that are required to be bifurcated from the underlying host instrument are accounted for and valued as separate financial instruments. At the inception of the derivative in 2017, the Company recognized this derivative as a liability and revenue was reduced by the initial fair value of the derivative liability. The Company remeasures the derivative liability to fair value at each reporting period and records the change in fair value of the derivative liability as other income (expense), net. The Company uses a present value analysis with multiple scenarios, which incorporates assumptions and estimates to value the derivative instrument. The Company assesses these assumptions and estimates on a periodic basis as additional information impacting the assumptions is obtained. Estimates and assumptions impacting the fair value measurement include the change of control payment to CFF (range of zero to $18.9 million at September 30, 2026 and December 31, 2025), the probability of a change of control event (range of 5.0% to 50.0% at September 30, 2026 and December 31, 2025), the probability of the product achieving development or commercial status at time of change of control (range of 4.8% to 17.2% at September 30, 2026 and December 31, 2025) and the discount rate of 15% at September 30, 2026 and December 31, 2025. The Company determined the estimated fair value of this liability as of the inception date of the CFF Agreement and concluded that the amount was immaterial. The Company determined the fair value of this derivative liability was $0.4 million as of each of September 30, 2026 and December 31, 2025. See Note 3, Fair Value Measurements and Marketable Securities, and Note 6, Research and Collaboration Arrangements for further discussion of the fair value of the embedded derivative.

17. California Institute for Regenerative Medicine Award

On April 12, 2026, the Company received a Notice of Award (the "Notice of Award") from the California Institute for Regenerative Medicine (“CIRM”) for a grant of approximately $5.9 million (the “CIRM Grant”), to support the early stage development of the proprietary adeno-associated virus (AAV) gene therapy candidate for the treatment of Alpha-1 Antitrypsin (AAT) Deficiency. The CIRM Grant is payable to the Company upon achievement of certain early stage developmental milestones. CIRM could permanently cease disbursements if milestones are not met within four months of the scheduled completion date. Additionally, if CIRM determines, in its sole discretion, that the Company has not complied with the terms and conditions of the CIRM Grant, CIRM may suspend or permanently cease disbursements. Funds received under the CIRM Grant may only be used for allowable project costs specifically identified with the CIRM-funded project. Project costs can include, but are not limited to, salary for personnel, supplies, consultants and clinical study costs. The Company will co-fund the research project in the amount of $1.4 million for such project costs under the terms of the CIRM Grant. Any unused funds must be returned to CIRM upon completion or termination of the project. The Company received an initial payment of $1.0 million from CIRM upon receipt of the Notice of Award.

Proceeds from the CIRM Grant are recognized over the period necessary to match the related research and development expense when it is probable that the Company has complied with the CIRM Grant conditions and will receive the proceeds pursuant to the milestones defined in the Notice of Award as reimbursement of those expenditures. The CIRM Grant proceeds, if any, received in advance of having incurred the related research and development expense are recorded in deferred grant reimbursements and recognized as an offset against research and development expense on the Company’s condensed statements of operations when the related research and development expenses are incurred.

During the nine months ended September 30, 2026, the Company achieved the first developmental milestone and became entitled to a reimbursement of $3.1 million. As of September 30, 2026, the Company recognized a deferred grant reimbursement of $3.6 million related to the CIRM grant on its condensed balance sheet, as the grant reimbursement exceeds the amount of grant reimbursement income recognized during the nine months ended September 30, 2026. During the three and nine months ended September 30, 2026, the Company recognized $0.4 million and $0.5 million, respectively, of grant reimbursements as a reduction of research and development expense related to the CIRM Grant on its condensed statement of operations.

18. Related Party Transactions

In March 2024, the Company entered into a research and option agreement (the “Reignite Agreement”) with Reignite Therapeutics Inc. (“Reignite”), which was founded by David Kirn, M.D., Chief Executive Officer of the Company. Reignite has the expertise to develop high-capacity, helper-dependent adenovirus capsids which the Company plans to utilize as it expands its therapeutic capsid evolution platform. Reignite and the Company plan to collaborate on a program to develop these high-capacity, helper-dependent adenovirus capsids. Under the Reignite Agreement, the Company shall have the final authority to amend and make updates to the plan and budget of the program. Further, the Company is responsible for the funding of the related research which includes the budgeted full-time employees and CRO costs, equipment costs not to exceed $60,000 and all other costs, in total not to exceed $1.5 million in any year of the program. The Company will have an option to acquire up to three capsids resulting from the program. The Company shall pay to Reignite an option exercise fee of $1.0 million per selected capsid for which the Company has exercised its option. The maximum total amount payable is $3.0 million.

During the three and nine months ended September 30, 2026, the Company paid Reignite $0.2 million and $1.0 million, respectively, for services that are presented as research and development expenses on the Company's condensed statements of operations. During the three and nine months ended September 30, 2025, the Company paid Reignite $0.2 million and $0.8 million, respectively, for services that are presented as research and development expenses on the Company's condensed statements of operations. As of September 30, 2026, the Company recognized a $0.2 million accrual for unpaid research and development expense, which is presented with accrued and other current liabilities on the Company's condensed balance sheet. No option exercise fees were incurred during the three and nine months ended September 30, 2026.

19. 401(k) Plan

In 2014, the Company adopted a 401(k) plan for all employees who have met certain eligibility requirements. The 401(k) plan allows employees to make pre-tax and post-tax contributions up to the maximum allowable amount set by the Internal Revenue Service. The Company made contributions to the 401(k) plan for all eligible participants and recorded contribution expenses of $0.6 million and $1.8 million for the three and nine months ended September 30, 2026, respectively, and $0.4 million and $1.5 million for the three and nine months ended September 30, 2025, respectively.

20. Segment Information

The Company operates in a single operating and reportable segment, which includes all activities related to discovery, development and commercialization of durable and disease-targeted therapeutics. The determination of a single business segment is consistent with the financial information regularly provided to the Company's chief operating decision maker (the "CODM"), who manages the business activities on a consolidated basis. The Company's CODM is its Chief Executive Officer who assesses performance for the business and decides how to allocate resources based on net loss that also is reported on the statements of operations. In making this assessment, the CODM reviews and evaluates net loss to monitor budget versus actual results and to analyze cash flows for purposes of allocating resources and assessing financial performance.

In addition to the significant expense categories included within net loss presented in the Company's condensed statements of operations, the following table provides disaggregated amounts that comprise research and development expenses that are regularly provided to the CODM (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Direct research and development expenses for 4D-150	$ 43,139	$ 25,020	$ 129,419	$ 56,927
Unallocated personnel costs (including stock-based compensation)	16,887	15,295	47,413	50,394
All other costs	9,750	9,123	26,206	30,767
Total research and development expenses	$ 69,776	$ 49,438	$ 203,038	$ 138,088

Effective in the first quarter of 2026, the Company updated the presentation of segment operating expenses provided to the CODM. This change in the presentation reflects how segment information is currently reviewed by the CODM. Prior period segment information has been recast to conform to the current period presentation.

The measure of segment assets is reported on the balance sheets as total assets. As of and for the nine months ended September 30, 2026 and 2025, all of the Company’s long-lived assets were located in the United States. The Company's revenues by geographic region, based on the location of the customer, are disclosed in Note 2, Summary of Significant Accounting Policies.

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 our condensed financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q (this "report"). This discussion and analysis and other parts of this report contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the section titled "Risk Factors" and elsewhere in this report.

Overview

We are a leading late-stage biotechnology company advancing durable and disease-targeted therapeutics with potential to transform treatment paradigms and provide unprecedented benefits to patients. Our primary focus is advancing 4D-150 for wet age-related macular degeneration ("wet AMD") and diabetic macular edema ("DME") through late-stage studies and potential commercialization. In addition, we are advancing our other pipeline programs, 4D-175 for geographic atrophy, 4D-710 for cystic fibrosis ("CF") lung disease, and 4D-725 for alpha-1-antitrypsin deficiency ("AATD") lung disease primarily through strategic funding alternatives. We believe we are well positioned to discover, develop, manufacture, and if approved, commercialize targeted genetic medicines with the potential to transform the lives of patients suffering from debilitating diseases.

Our lead product candidate 4D-150 utilizes our proprietary R100 vector and a transgene encoding anti-VEGF biologics: aflibercept and an RNA interference (RNAi) approach targeting VEGF-C. The goal for our development and potential commercialization of 4D-150 is to transform the standard of care for large market VEGF-driven retinal diseases with a routine in-office lifelong backbone therapy that substantially reduces treatment burden to enable improved long-term vision outcomes. 4D-150 is initially being developed for the treatment of wet AMD and DME.

In March 2025, we initiated 4FRONT-1, our first Phase 3 trial of 4D-150 in wet AMD. Subsequently in February 2026, we announced enrollment completion within an approximately 11-month period, ahead of initial projections, with the clinical trial overenrolled and 523 patients randomized, reflecting strong interest from investigators and patients. We anticipate topline data for 4FRONT-1 in the second quarter of 2027.

Additionally, in June 2025, we initiated 4FRONT-2, our second Phase 3 trial of 4D-150 in wet AMD. 4FRONT-2 is a global clinical trial and enrolled both treatment-naïve and recently diagnosed, treatment-experienced patients. We completed enrollment for 4FRONT-2 in June 2026 with 531 patients randomized. We anticipate topline data for 4FRONT-2 in the second half of 2027.

In November 2025 and July 2026, we announced positive long-term results from the ongoing 4D-150 PRISM Phase 1/2 clinical trial in wet AMD. 4D-150 demonstrated consistent and durable benefit across all three patient cohorts as evidenced by maintenance of visual acuity, control of retinal anatomy and clinically meaningful reduction of treatment burden at all time points with 2 years of follow-up. In addition, a consistent dose response was observed between 3E10 vg/eye, the selected Phase 3 dose, and the lower dose of 1E10 vg/eye. The Phase 3 dose achieved clinically meaningful reductions in treatment burden. No new cases of intraocular inflammation were reported during this follow-up period with up to approximately 4 years of follow-up.

In September 2026, we initiated 4SIGHT, our global Phase 3 trial of 4D-150 in DME. The FDA, EMA and Japan Pharmaceuticals and Medical Devices Agency ("PMDA") are aligned on a proposed single Phase 3 clinical trial for the licensure of 4D-150 in DME in conjunction with data generated from the 4FRONT-1 and 4FRONT-2 wet AMD Phase 3 trials.

In September 2026, we presented updated 2-year results from the 4D-150 SPECTRA Part 1 clinical trial in DME. 4D-150 continued to be well tolerated with no intraocular inflammation observed at any timepoint or dose level. In addition, 4D-150 demonstrated durable and dose-dependent clinical activity with sustained gains in visual acuity and control of retinal anatomy and a clinically meaningful reduction in treatment burden.

In October 2025, we entered into a Collaboration and License Agreement (the “Otsuka Agreement”) with Otsuka Pharmaceutical Co., Ltd. ("Otsuka") pursuant to which we granted Otsuka exclusive rights to develop and commercialize 4D-150 for retinal diseases, including wet AMD and DME, in Japan, Korea, China, Australia, and other Asia-Pacific markets (the "Otsuka Territory"). Otsuka has agreed to lead all regulatory and commercialization activities in the Otsuka Territory. We have agreed to continue to lead all Phase 3 clinical activity globally, including within the Otsuka Territory. Otsuka made an upfront cash payment of $85.0 million and agreed to provide certain cost sharing for global development activities. In addition, we are eligible for up to $335.5 million in potential regulatory and commercial milestone payments and tiered double-digit royalties depending on net sales in the Otsuka Territory. We retain full development and commercialization rights for 4D-150 outside the Otsuka Territory, including the United States, Latin America, and Europe.

Our other retina pipeline program is 4D-175, which utilizes the intravitreal R100 AAV vector and a codon-optimized transgene encoding a highly functional shortened form of human complement factor H (sCFH) for treatment of geographic atrophy. The sCFH payload is designed to restore normal complement regulation, which has the potential to slow progression of disease. We currently maintain an active IND and continue to evaluate strategic funding alternatives to advance the program into the clinic.

Our most advanced pulmonary pipeline program is 4D-710, which we believe is the first known genetic medicine to demonstrate successful delivery and durable expression of the cystic fibrosis transmembrane conductance regulator (“CFTR”) transgene in the lungs of people with cystic fibrosis ("CF") and is currently in Phase 2 development. We believe these results will translate into durable clinical improvements in people with CF, including improved lung function and quality of life. In October 2025, we announced a funding agreement with the Cystic Fibrosis Foundation ("CFF") to provide up to $11.0 million in additional funding, including $7.5 million in an initial tranche, which was completed in October 2025. The proceeds of this funding agreement enabled the start of the Phase 2 stage of the AEROW clinical trial, redosing, and Phase 3 readiness activities.

We have funded our operations primarily through the sale and issuance of equity securities, from borrowings under our loan facility with Hercules Capital, Inc. and, to a lesser extent, from cash received pursuant to our collaboration and license agreements.

We have incurred significant operating losses. Our net losses were $78.1 million and $56.9 million for the three months ended September 30, 2026 and 2025, respectively, and $219.8 million and $159.5 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $936.1 million. We do not expect positive cash flows from operations in the foreseeable future. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We do not have any products approved for sale and have not generated any revenue from product sales since our inception. Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates, if approved.

We will require substantial additional funding to support our continuing operations and further the development of our product candidates. 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, which could include income from collaborations, strategic partnerships, or other strategic arrangements, for the foreseeable future. Adequate funding may not be available when needed or on terms acceptable to us, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from conflicts in the Middle East, the war in Ukraine, rising interest rates, tariffs, inflation, government shutdowns and otherwise. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Components of Results of Operations

Revenue

Our revenue to date has been generated through payments from our collaboration and license agreements, primarily from upfront and milestone payments and clinical trial cost sharing and expense reimbursement amounts. We have not generated any revenue from the sale of approved products and do not expect to do so for the foreseeable future.

In October 2025, we entered into the Otsuka Agreement pursuant to which we granted Otsuka exclusive rights to develop and commercialize 4D-150 for retinal diseases, including wet AMD and DME, in the Otsuka Territory. Otsuka made an upfront cash payment of $85 million which we recognized as revenue during the fourth quarter of 2025, and agreed to provide certain cost sharing for global development activities.

Future collaboration and license revenue is highly dependent on the successful development and commercialization of products by our collaboration partners, which is uncertain, and revenue may fluctuate significantly from period to period. Additionally, we may never receive the consideration from our license agreements that is contemplated for option fees, development and sales-based milestone payments or royalties on sales of licensed products, given the contingent nature of these payments.

Operating Expenses

Research and Development

Our research and development expenses primarily consist of costs incurred for the discovery and preclinical and clinical development of our product candidates. These expenses include salaries and personnel-related costs, including stock-based compensation of our clinical, medical, chemistry, manufacturing and controls and scientific personnel performing research and development activities; laboratory supplies; research materials; fees paid to CROs to execute preclinical studies and clinical trials; fees paid to CDMOs to manufacture materials for preclinical studies and clinical trials; fees related to obtaining technology licenses; consulting costs; costs related to seeking regulatory approval of our product candidates; and allocated facility-related costs, information technology costs, depreciation expense, and other overhead.

We expense all research and development costs in the periods in which they are incurred. We have entered into various agreements with CROs and CDMOs. Costs of certain activities are recognized based on an evaluation of the progress to completion of specific tasks. Payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses and other current assets on our balance sheet. The capitalized amounts are recognized as expense as the goods are delivered or the related services are performed.

We do not allocate our internal costs, such as salary and other personnel-related expenses, laboratory supplies and allocated overhead by product candidate. In particular, with respect to internal costs, several of our departments support multiple product candidate research and development programs and, therefore, the costs cannot be allocated to a particular product candidate or development program.

At this time, we cannot reasonably estimate or know the nature, timing or estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. The process of conducting the necessary clinical development to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. See the section titled “Risk Factors” for additional risks regarding regulatory development and approval.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses, including salaries, employee benefit costs and stock-based compensation expense for our personnel in executive, finance and accounting, legal, human resources, business development, and other administrative functions. General and administrative expenses also include professional fees for legal, patent, consulting, accounting and tax services, allocated overhead, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses.

Other Income, Net

Our other income, net primarily consists of interest income earned on our cash, cash equivalents and marketable securities, adjustments for the change in the fair value of our derivative liability which must be remeasured at each reporting date and interest expense under the Loan and Security Agreement with Hercules Capital, Inc.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2026 and 2025

The following tables summarize our results of operations for the periods indicated (dollars in thousands):

	Three Months Ended September 30,			
	2026	2025	$ Change	% Change
Revenue				
Collaboration and license revenue	$ 4,145	$ 90	$ 4,055	*
Operating Expenses:				
Research and development	69,776	49,438	20,338	41%
General and administrative	15,587	11,837	3,750	32%
Total operating expenses	85,363	61,275	24,088	39%
Loss from operations	(81,218)	(61,185)	(20,033)	33%
Other Income, Net	3,162	4,309	(1,147)	(27)%
Net loss	$ (78,056)	$ (56,876)	$ (21,180)	37%

* not meaningful

	Nine Months Ended September 30,			
	2026	2025	$ Change	% Change
Revenue				
Collaboration and license revenue	$ 10,974	$ 119	$ 10,855	*
Operating Expenses:				
Research and development	203,038	138,088	64,950	47%
General and administrative	39,798	36,293	3,505	10%
Total operating expenses	242,836	174,381	68,455	39%
Loss from operations	(231,862)	(174,262)	(57,600)	33%
Other Income, Net	12,111	14,756	(2,645)	(18)%
Net loss	$ (219,751)	$ (159,506)	$ (60,245)	38%

* not meaningful

Revenue

Revenue increased by $4.1 million and $10.9 million during the three and nine months ended September 30, 2026 compared to the same periods in 2025, respectively, primarily due to clinical development programs costs sharing and reimbursement amounts from Otsuka.

Research and Development Expenses

The following table provides a breakout of research and development expenses for the periods indicated (dollars in thousands):

	Three Months Ended September 30,			
	2026	2025	$ Change	% Change
Direct research and development expenses for 4D-150	$ 43,139	$ 25,020	$ 18,119	72%
Unallocated personnel costs (including stock-based compensation)	16,887	15,295	1,592	10%
All other costs	9,750	9,123	627	7%
Total research and development expenses	$ 69,776	$ 49,438	$ 20,338	41%

	Nine Months Ended September 30,			
	2026	2025	$ Change	% Change
Direct research and development expenses for 4D-150	$ 129,419	$ 56,927	$ 72,492	127%
Unallocated personnel costs (including stock-based compensation)	47,413	50,394	(2,981)	(6)%
All other costs	26,206	30,767	(4,561)	(15)%
Total research and development expenses	$ 203,038	$ 138,088	$ 64,950	47%

Research and development expenses increased by $20.3 million, or 41%, and $65.0 million, or 47%, during the three and nine months ended September 30, 2026 compared to the same periods in 2025, respectively. The increase was primarily due to the progression of clinical and manufacturing activities for wet AMD and DME.

General and Administrative Expenses

General and administrative expenses increased by $3.8 million, or 32%, and $3.5 million, or 10%, during the three and nine months ended September 30, 2026 compared to the same periods in 2025, respectively. The increase was primarily due to an increase in headcount and one-time incremental stock-based compensation expense from modifications.

Other Income, Net

Other income, net, decreased by $1.1 million, or 27%, and $2.6 million, or 18%, during the three and nine months ended September 30, 2026 compared to the same periods in 2025, respectively. The decrease was attributed to a combination of a lower interest income due to a lower average balance of cash, cash equivalents and marketable securities and interest expense associated with the Loan and Security Agreement entered into with Hercules Capital, Inc. in June 2026.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2026, we had cash, cash equivalents and marketable securities of $375.0 million. We have funded our operations primarily through the sale and issuance of our equity securities, including Follow-on Offerings and our “at-the-market” offering program, from borrowings under our Loan and Security Agreement and, to a lesser extent, from cash received pursuant to our collaboration and license agreements. Our recent sources of liquidity include the following transactions:

Follow-on Offerings

In November 2025, we completed an underwritten offering (the "2025 Offering") in which 8,385,809 shares of our common stock were sold at an offering price of $10.51 per share, as well as pre-funded warrants to purchase 1,128,949 shares of our common stock at an offering price of $10.5099 per underlying share. The net proceeds from the 2025 Offering were approximately $93.3 million, after deducting the underwriting discounts and commissions and other offering expenses.

At-the-Market Offering Program

In June 2024, we entered into a Sales Agreement (the "Leerink Sales Agreement") with Leerink Partners LLC ("Leerink") as sales agent to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to $250.0 million pursuant to a Registration Statement on Form S-3 that we filed with the SEC in February 2024, and subsequently amended in February 2025, as an "at-the-market" offering under the Securities Act. For the year ended December 31, 2025, 1,175,000 shares of our common stock were sold pursuant to the Leerink Sales Agreement for net proceeds to us of $9.6 million, after deducting issuance costs. For the nine months ended September 30, 2026, 3,518,472 shares were sold pursuant to the Leerink Sales Agreement for net proceeds to us of $31.6 million, after deducting issuance costs.

Collaboration and License Agreements

In October 2025, we entered into a Collaboration and License Agreement with Otsuka where we granted Otsuka exclusive rights to develop and commercialize 4D-150 for retinal diseases, including wet AMD and DME, in the Otsuka Territory. Otsuka made an upfront cash payment of $85 million which we recognized as revenue during the fourth quarter of 2025, and agreed to provide certain cost sharing for global development activities.

Loan and Security Agreement

In June 2026, we entered into a Loan and Security Agreement (the "Loan and Security Agreement") with Hercules Capital, Inc., providing for up to $200.0 million in term loan borrowings. At the closing on June 24, 2026, we had access to a $50.0 million tranche, of which we borrowed $20.0 million. The remaining $30.0 million is available, at our option, through June 15, 2027. We may draw up to an additional $100.0 million in three separate tranches upon achievement of certain clinical, regulatory, financing and capitalization milestones. As of September 30, 2026, we had not met the requirements to access the funds under these tranches, as it had not achieved the related milestone. An additional fifth tranche of $50.0 million may be made available upon our request and at Hercules' sole discretion and is not contingent upon our achievement of the milestones applicable to the prior tranches. The Loan and Security Agreement matures on June 1, 2031. The initial borrowing of $20.0 million bears interest at a floating rate equal to the greater of (i) the prime rate plus 2.0% and (ii) 8.75%, and all future borrowings, including the available balance of $30.0 million of the $50.0 million tranche available as of June 24, 2026, bear interest at a floating rate equal to the greater of (i) the prime rate plus 2.5% and (ii) 9.25%. The floating interest rate is capped at 0.75% more than the interest rate at the time of the borrowing. We are required to make monthly interest-only payments for borrowings under the initial tranche of $50.0 million for a period of 29 months, which may be extended by up to an additional 30 months upon achievement of certain clinical, regulatory, financing and capitalization milestones.

The Loan and Security Agreement includes an end-of-term charge ranging from 3.70% to 6.50% of the aggregate principal amount, depending on the timing of the repayment. We may voluntarily prepay outstanding borrowings, subject to prepayment premiums ranging from 1.0% to 3.0% of the principal amount prepaid, depending on the timing of repayment. In connection with the Loan and Security Agreement, we paid a $0.5 million initial facility fee and incurred approximately $2.1 million of debt issuance costs, consisting primarily of lender fees and third-party legal and other transaction costs.

The Loan and Security Agreement contains financial covenants, including minimum cash and performance-based covenants, that are not yet subject to testing or effective as of September 30, 2026. Upon the occurrence of certain events and beginning no earlier than January 1, 2028, we may become subject to minimum cash and performance-based financial covenants. The Loan and Security Agreement contains customary events of default, including failure to make required payments or maintain compliance with covenants, breach, default, insolvency, attachment or judgment events and any circumstance which could reasonably be expected to have a material adverse effect on us. The Loan and Security Agreement also contains customary affirmative and restrictive covenants, representations and warranties associated with a secured loan facility, including certain limitations on indebtedness, liens, investments, distributions, mergers or acquisitions and corporate changes.

As of September 30, 2026, the outstanding principal under the Loan and Security Agreement was $20.0 million, bearing interest at a rate of 9.00% per annum.

Future Funding Requirements

We have experienced recurring net losses and had an accumulated deficit of $936.1 million as of September 30, 2026. Our transition to profitability is dependent upon the successful development, approval and commercialization of our product candidates and those of our collaboration partners and achieving a level of revenue adequate to support our cost structure. We expect to continue to incur losses for the foreseeable future.

We expect that our overall research and development and general and administrative expenses will increase. As a result, we will need significant additional capital to fund our operations, which we may obtain through one or more equity offerings, debt financings or other third-party funding, the Otsuka Agreement, and additional potential strategic alliances and licensing or collaboration arrangements.

Because of the numerous risks and uncertainties associated with the development and commercialization of gene therapy product candidates, we are unable to estimate the amount of increased capital we will need to raise to support our operations and the outlays and operating expenditures necessary to complete the development of our product candidates and build additional manufacturing capacity, and we may use our available capital resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including:

- the progress of our current and future product candidates through preclinical and clinical development;
- potential delays in our preclinical studies and clinical trials, whether current or planned;
- working with our contract manufacturers to scale up the manufacturing processes for our product candidates;
- continuing our research and discovery activities;
- continuing the development of our Therapeutic Vector Evolution platform;
- initiating and conducting additional preclinical, clinical or other studies for our product candidates;
- changing or adding additional contract manufacturers or suppliers;
- seeking regulatory approvals and marketing authorizations for our product candidates;
- establishing sales, marketing and distribution infrastructure to commercialize any products for which we obtain approval;
- acquiring or in-licensing product candidates, intellectual property and technologies;

- making milestone, royalty or other payments due under any current or future collaboration or license agreements;
- receiving milestone, royalty or other payments under any current or future collaboration or license agreements;
- obtaining, maintaining, expanding, protecting and enforcing our intellectual property portfolio;
- attracting, hiring and retaining qualified personnel;
- potential delays or other issues related to our operations;
- meeting the requirements and demands of being a public company;
- defending against any product liability claims or other lawsuits related to our products; and
- adverse macroeconomic conditions such as, but not limited to, higher inflation, tariffs, government shutdowns and increased interest rates, each of which may exacerbate the magnitude of the factors discussed above.

We believe that our existing cash, cash equivalents and marketable securities will allow us to fund our planned operations for at least one year from the date of the issuance of the condensed financial statements included in this report.

We have based our estimates as to how long we expect we will be able to fund our operations on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect, in which case we would be required to obtain additional financing sooner than currently projected, which may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. See the section titled “Risk Factors” for additional risks associated with our substantial capital requirements.

We have limited committed external sources of funds. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to complete the clinical development for the product candidates for treatment of wet AMD, DME, geographic atrophy, cystic fibrosis lung disease, alpha-1 antitrypsin deficiency lung disease or any other indication we may pursue. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter would result in fixed payment obligations and may involve agreements that include grants of security interests on our assets and restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, granting liens over our assets, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. Any debt financing or additional equity that we raise may contain terms that could adversely affect our common stockholders. Further, additional funds may not be available when we need them, on terms that are acceptable to us, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the war in Ukraine, conflicts in the Middle East, any expansion of these conflicts, rising interest rates, tariffs, inflation, natural disasters, government shutdowns and pandemics.

If we are unable to obtain additional funding, we expect to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or investment in manufacturing capabilities, which could adversely affect our business. If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

Summary Statement of Cash Flows

The following is a summary of cash flows for the periods indicated below (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash used in operating activities	$ (194,835)	$ (137,633)
Net cash provided by investing activities	119,271	35,874
Net cash provided by financing activities	54,427	978
Net decrease in cash and cash equivalents	$ (21,137)	$ (100,781)

Net Cash Used in Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2026 and 2025 was $194.8 million and $137.6 million, respectively. The increase in net cash flows used in operating activities for the nine months ended September 30, 2026, reflects activities to support our two Phase 3 programs in wet AMD and one in DME, as well as increases in employee costs to support our Phase 3 programs.

Net Cash Provided by Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2026 and 2025 was $119.3 million and $35.9 million, respectively, consisting of net cash inflows for the purchases and maturities of marketable securities. During the nine months ended September 30, 2026, we invested the proceeds from our equity and debt financings. Our other investing activities were not significant for the periods presented.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2026 and 2025 was $54.4 million and $1.0 million, respectively. During the nine months ended September 30, 2026, we received proceeds of $31.6 million from the issuance of common stock pursuant to the Leerink Sales Agreement, proceeds of $19.3 million from the Loan and Security Agreement and proceeds of $3.5 million from the issuance of common stock related to our employee options and stock purchase plan. Our financing activities for the same period in prior year were due to proceeds from issuance of common stock related to our employee options and stock purchase plan.

Contractual Obligations, Commitments and Contingencies

We enter into various agreements in the ordinary course of business, such as those with suppliers, CROs, CDMOs and clinical trial sites. These contracts generally provide for termination on notice or may have a potential termination fee if a purchase order is canceled within a specified time. The total value of non-cancellable obligations under contracts was $4.3 million and $4.0 million as of September 30, 2026 and December 31, 2025, respectively. This presentation of non-cancellable purchase obligations does not include any estimates of potential reduction of such liabilities related to mitigation obligations of the counterparties in the event of cancellation under the terms of our engagements.

As of September 30, 2026, our principal commitments consisted of principal outstanding under the Loan and Security Agreement and obligations under our operating lease for our headquarters. Please see Note 8, Commitments and Contingencies and Note 9, Long-Term Debt, to our condensed financial statements included elsewhere in this report.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our condensed financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our condensed financial statements, as well as the reported revenue and expenses during the reported periods. We evaluate these estimates and assumptions on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

During the nine months ended September 30, 2026, there were no changes to our critical accounting policies and significant judgments and estimates as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2025.

Recent Accounting Pronouncements

See Note 2, Summary of Significant Accounting Policies, to our condensed financial statements included elsewhere in this report for information.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity and Effects of Inflation

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2026, we had cash, cash equivalents and marketable securities of $375.0 million, consisting of bank deposits, interest-bearing money market funds, and marketable securities, for which the fair value would be affected by changes in the general level of U.S. interest rates. However, due to the short to medium-term maturities of our cash equivalents and marketable securities, an immediate 10% change in interest rates would not have a material effect on the fair value of our cash equivalents or marketable securities.

As of September 30, 2026, we had $20.0 million outstanding under our Loan and Security Agreement, which bears interest at a floating rate. A hypothetical 50 basis point increase in interest rates would increase our annual interest expense by approximately $0.1 million, assuming the outstanding principal balance remained constant for the full year. We currently believe this impact would not be material to our financial condition or results of operations.

We do not believe that inflation or interest rate changes have had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures.

Evaluation of our Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial and accounting 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 our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our principal executive officer and principal financial and accounting officer, evaluated the effectiveness of our disclosure controls and procedures at the end of the period covered by this report. Based upon such evaluation, our principal executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2026, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

The legal proceedings information set forth in Note 8, Commitments and Contingencies, of the notes to our condensed financial statements in Part I, Item 1 of this report is incorporated by reference.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this report, including our condensed financial statements and the related notes and the section of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. If any of the following risks actually occur, our business, reputation, financial condition, results of operations, revenue and future prospects could be seriously harmed. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. Unless otherwise indicated, references to our business being seriously harmed in these risk factors and elsewhere will include harm to our business, reputation, financial condition, results of operations, future prospects and stock price. If our business is seriously harmed, the market price of our common stock could decline, and you could lose part or all of your investment.

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

We are in the late stages of drug development for our lead program and have a limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.

We are a leading late-stage biotechnology company advancing durable and disease-targeted therapeutics with the potential to transform treatment paradigms and provide unprecedented benefits to patients. We commenced operations in September 2013, have no products approved for commercial sale and have not generated any product revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. If our product candidates are not successfully developed and approved, we may never generate any product revenue. To date, we have not completed any clinical trials (including any pivotal clinical trial), obtained marketing approval for any product candidates, manufactured commercial scale quantities of any of our product candidates or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Our limited operating history as a company and stage of drug development make any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will be seriously harmed.

We have had recurring net losses, and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred recurring net losses, including net losses of $78.1 million and $56.9 million for the three months ended September 30, 2026 and 2025, respectively, and $219.8 million and $159.5 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $936.1 million.

We have devoted substantially all of our financial resources and efforts on research and development activities. We do not expect to generate revenue from product sales for several years, if at all. We continue to incur significant research and development and other expenses related to our ongoing operations. The amount of our future net losses will depend, in part, on the level of our future expenditures and our ability to generate revenue. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our expenses may increase substantially if and as we:

- progress our current and any future product candidates through preclinical and clinical development;
- expand our manufacturing facilities and work with our contract manufacturers to scale up the manufacturing processes for our product candidates;
- continue our research and discovery activities;
- continue the development of our Therapeutic Vector Evolution platform;
- initiate and conduct additional preclinical, clinical or other studies for our product candidates;
- change or add additional contract manufacturers or suppliers;
- seek regulatory approvals and marketing authorizations for our product candidates;
- establish sales, marketing and distribution infrastructure to commercialize any products for which we obtain approval;
- acquire or in-license product candidates, intellectual property and technologies;
- make milestone, royalty or other payments due under any current or future collaboration or license agreements;
- obtain, maintain, expand, protect and enforce our intellectual property portfolio;
- attract, hire and retain qualified personnel;
- experience any delays or encounter other issues related to our operations;
- meet the requirements and demands of being a public company;
- are adversely impacted by general economic conditions, such as rising inflation, tariffs, government shutdowns and increased interest rates;
- defend against any product liability claims or other lawsuits related to our products; and
- experience delays in our preclinical studies and clinical trials, whether current or planned, due to pandemics or public health emergencies.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' deficit and working capital. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time consuming, expensive and uncertain process that takes years to complete. Our operations have required substantial amounts of cash since inception. To date, we have financed our operations primarily through the sale of equity securities, from borrowings under our $200.0 million loan and security agreement (the "Loan Agreement") with Hercules Capital, Inc. ("Hercules"), and to a lesser extent from cash received pursuant to our collaboration and license agreements. We have initiated clinical trials, which are ongoing, and have additional product candidates in preclinical development that may enter clinical development. Developing our product candidates is expensive, and we expect to continue to spend substantial amounts as we fund our early-stage research projects, continue preclinical and clinical development of our product candidates and, in particular, advance our product candidates through clinical trials. Even if we are successful in developing our product candidates, obtaining regulatory approvals and launching and commercializing any product candidate will require substantial funding.

As of September 30, 2026, we had $375.0 million in cash and cash equivalents and marketable securities.

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will allow us to fund our planned operations for at least one year from the date of the issuance of the condensed financial statements included in this report.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. Our ability to raise additional capital may be adversely impacted by global economic conditions affecting credit and financial markets (including due to increased interest rates and high inflation rates) and product supply chains. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities or eliminate one or more of our development programs altogether; or
- delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to, or jointly own some aspects of, our product candidates or technologies that we would otherwise pursue on our own. We do not expect to realize revenue from sales of products or royalties from licensed products in the foreseeable future, if at all, and unless and until a product candidate is clinically tested, approved for commercialization and successfully marketed.

We will be required to seek additional funding in the future and currently intend to do so through collaborations, public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available to us on acceptable terms or at all. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution, and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. Any of the above events could seriously harm our business and cause the price of our common stock to decline.

Due to the significant resources required for the development of our product candidates, and depending on our ability to access capital, we must prioritize development of certain product candidates. Moreover, we may expend our limited resources on product candidates that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our product candidates, in particular our product candidates in IND-enabling studies and those in clinical trials, we must decide which product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain product candidates may subsequently also prove to be less than optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the biopharmaceutical industry, particularly in retina and pulmonology, our business could be seriously harmed. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

The amount of our future losses is uncertain and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly, making it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside our control and may be difficult to predict, including:

- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or collaboration partners;
- the timing, cost, and level of investment in research, development and commercialization activities, which may change from time to time;
- the timing of receipt of approvals from regulatory authorities in the United States and internationally;
- the timing and status of enrollment and safety and efficacy readouts for our clinical trials;
- the cost of manufacturing, as well as building out our supply chain, which may vary depending on the quantity of production, the cost of continuing to establish and scale up our manufacturing capabilities, and the terms of any agreements we enter into with third-party suppliers;
- the timing and amount of any option, milestone, royalty or other payments due under any current or future collaboration or license agreement;

- coverage and reimbursement policies with respect to our genetic medicine product candidates and potential future drugs that compete with our products, if approved;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- the level of demand for our genetic medicine products, if approved, which may vary significantly over time;
- future accounting pronouncements or changes in our accounting policies; and
- the impact from general macroeconomic trends, such as higher inflation, tariffs, government shutdowns and increased interest rates.

The cumulative effects 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 financial analysts or investors for any period. If our revenue or operating results fall below or if operating expenses or other costs are higher than the expectations of analysts or investors or below or above, as the case may be, 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 revenue or earnings guidance we may provide.

Our loan and security agreement with Hercules contains operating and financial covenants that may restrict our business and financing activities, is secured by substantially all of our assets, including our intellectual property, and we may be required to repay our outstanding indebtedness earlier than we expect, any of which could have a material adverse effect on our business.

In June 2026, we entered into the Loan Agreement with Hercules, which provides for term loans in an aggregate principal amount of up to $200.0 million, of which $20.0 million was funded at closing. The term loans bear interest at floating rates based on the prime rate, subject to specified floors, payable monthly in arrears, and mature on June 1, 2031. Increases in the prime rate would increase our debt service obligations, and servicing our indebtedness will require a substantial amount of cash and will reduce the funds available for our operations. In addition, of the amounts not funded at closing, $30.0 million is available at our election only until June 15, 2027, $100.0 million is available only upon the achievement of specified milestones and $50.0 million is available only in Hercules' sole discretion. Accordingly, we may never have access to the full amount of the facility, and we cannot be certain that the milestones will be achieved or that Hercules will elect to make discretionary amounts available to us.

The Loan Agreement contains customary affirmative and restrictive covenants that, among other things, limit our ability to transfer or dispose of assets, merge with other companies or consummate certain changes of control, make investments, incur additional indebtedness and liens and enter into new businesses. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of Hercules or terminate the Loan Agreement, which may limit our operating flexibility. It also contains financial covenants, including a minimum cash covenant that, beginning on the earlier of specified dates or aggregate borrowing thresholds, will require us to maintain cash equal to a specified percentage of our outstanding obligations under the Loan Agreement, except on any day on which our market capitalization exceeds seven times such obligations, as well as a requirement to maintain cash equal to at least 125% of our outstanding obligations if we effect a cash redemption of any permitted convertible debt. The Loan Agreement also contains a performance covenant that, beginning nine months after both FDA approval of our lead product candidate and aggregate borrowings equaling or exceeding $75.0 million, will require us to satisfy at least one of (1) a combination of a market capitalization test and a minimum cash test, (2) a minimum cash test, or (3) a net product revenue test. Because the applicability of the minimum cash covenant, and our ability to satisfy the market capitalization prong of the performance covenant, depend in part on our market capitalization, a decline in the trading price of our common stock, which may occur for reasons unrelated to our business or results of operations, could cause the minimum cash covenant to apply, or make the performance covenant more difficult to satisfy, at times when they otherwise would not. These covenants could restrict our ability to operate our business and pursue our business strategies, and we may not be able to comply with these covenants in the future. If the minimum cash covenant becomes applicable, a portion of our cash will effectively be unavailable to fund our operations, and any failure to comply with the covenants in the Loan Agreement could result in an event of default.

Our obligations under the Loan Agreement are secured by a security interest in substantially all of our assets, including our intellectual property, and certain of our future subsidiaries may be required to guarantee our obligations and pledge substantially all of their assets, including intellectual property, to secure such guarantees. Upon the occurrence of an event of default, Hercules may accelerate all of our outstanding obligations, including principal, interest and any applicable prepayment charges and end of term charges, and our obligations will be automatically accelerated upon certain insolvency, liquidation, bankruptcy or similar events. If our obligations are accelerated, we may not have sufficient cash to repay them, and Hercules could foreclose on the collateral, including intellectual property that is critical to our business. Any voluntary prepayment of the term loans is also subject to prepayment and end of term fees, which could make it more costly for us to refinance the facility. In addition, because our assets, including our intellectual property, are pledged to Hercules, our ability to obtain additional debt or other secured financing may be limited, and any future financing may be more difficult or costly to obtain.

Risks Related to the Research, Discovery, Development and Commercialization of Our Product Candidates

All of our product candidates are based on a novel AAV genetic medicine technology with which there is limited regulatory and clinical experience to date, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval. Further, the regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied therapeutic modalities.

All of our product candidates are based on genetic medicine technology, and our future success depends on the successful development of this novel therapeutic approach. We cannot assure you that any development problems we or other genetic medicine companies experience in the future related to genetic medicine technology will not cause significant delays or unanticipated costs in the development of our product candidates, or that such development problems can be solved. In addition, the clinical study requirements of the FDA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied therapeutic modalities. Further, as we are developing novel treatments for diseases in which there is limited clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, EMA or comparable foreign regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. To date, few genetic medicine products have been approved by the FDA or comparable foreign regulatory authorities, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States, the European Union ("EU") or other jurisdictions. Further, approvals by one regulatory agency may not be indicative of what other regulatory agencies may require for approval.

Regulatory requirements governing genetic medicine products have evolved and may continue to change in the future. For example, the FDA has established the Office of Therapeutic Products within its Center for Biologics Evaluation and Research ("CBER") to consolidate the review of genetic medicine and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. These and other regulatory review agencies, committees and advisory groups and the requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval limitations or restrictions.

The National Institutes of Health ("NIH") Guidelines for Research Involving Recombinant DNA Molecules ("NIH Guidelines") require supervision of human gene transfer trials, including evaluation and assessment by an Institutional Biosafety Committee ("IBC"), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

We are subject to significant regulatory oversight by the FDA, and, in addition, the applicable IBC and Institutional Review Board ("IRB"), of each institution at which we or our collaborators conduct clinical trials of our product candidates, or a central IRB if appropriate, need to review and approve the proposed clinical trial.

Similar requirements apply in the EU. The EMA has a Committee for Advanced Therapies ("CAT") that is responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products, or ATMP(s). ATMPs include gene therapy medicines, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for an ATMP candidate that is submitted to the EMA. In the EU, the development and evaluation of an ATMP must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. Similarly complex regulatory environments exist in other jurisdictions.

Changes in applicable regulatory guidelines may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions.

As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all, and could seriously harm our business.

Adverse public perception or regulatory scrutiny of genetic medicine technology may negatively impact the developmental progress or commercial success of product candidates that we develop alone or with collaborators.

The developmental and commercial success of our current product candidates, or any that we develop alone or with collaborators in the future, will depend in part on public acceptance of the use of genetic medicine technology, including the use of AAVs, for the prevention or treatment of human diseases. Adverse public perception of gene therapies may negatively impact our ability to raise capital or enter into strategic agreements for the development of product candidates.

Genetic medicine remains a novel technology. The commercial success of our genetic medicine product candidates, if successfully developed and approved, may be adversely affected by claims that genetic medicine is unsafe, unethical or immoral. This may lead to unfavorable public perception and the inability of any of our product candidates to gain the acceptance of the public or the medical community. Unfavorable public perceptions may also adversely impact our or our collaborators' ability to enroll clinical trials for our product candidates. Moreover, success in commercializing any product candidates that receive regulatory approval will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of such product candidates in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

Publicity of any adverse events in, or unfavorable results of, preclinical studies or clinical trials for any current or future product candidates, or with respect to the studies or trials of our competitors or of academic researchers utilizing similar technologies, even if not ultimately attributable to our technology or product candidates, could negatively influence public opinion. Negative public perception about the use of AAV technology in human therapeutics, whether related to our technology or a competitor's technology, could result in increased governmental regulation, delays in the development and commercialization of product candidates or decreased demand for the resulting products, any of which may seriously harm our business.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product 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 other comparable foreign regulatory authorities.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Less common adverse effects may not become evident until investigational products are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval.

If any serious adverse events occur, clinical trials or commercial distribution of any product candidates or products we develop alone or with collaborators could be suspended or terminated, and our business could be seriously harmed. Treatment-related side effects could also affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us or our collaborators to cease further development of, deny approval of, or require us to cease selling any product candidates or products for any or all targeted indications. If we or our collaborators elect, or are required, to delay, suspend or terminate any clinical trial or commercialization efforts, the commercial prospects of such product candidates or products may be harmed, and our ability to generate product revenue from them or other product candidates that we develop may be delayed or eliminated. Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a Risk Evaluation and Mitigation Strategy (“REMS”), which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- the product may become less competitive;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could seriously harm our business.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have no products approved for commercial sale, and we have never generated any revenue from product sales, and we may never generate product revenue or be profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales. We do not anticipate generating any revenue from product sales until after we have successfully completed clinical development and received regulatory approval for the commercial sale of a product candidate, which will not occur for several years, if ever.

Our ability to generate revenue and achieve profitability depends significantly on many factors, including:

- successfully completing research and preclinical and clinical development of our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we successfully complete clinical development and clinical trials;
- developing a sustainable and scalable manufacturing process for our product candidates, as well as establishing and maintaining commercially viable supply relationships with third parties that can provide adequate products and services to support clinical activities and any commercial demand for our product candidates;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- launching and successfully commercializing product candidates for which we obtain marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;
- obtaining and maintaining an adequate price for our product candidates, both in the United States and in foreign countries where our product candidates are commercialized;
- obtaining adequate reimbursement for our product candidates or procedures using our product candidates from payors;
- the convenience and durability of our treatment or dosing regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates, or any future product candidates, if approved, including relative to alternative and competing treatments;
- patient demand for any of our product candidates that may be approved;
- addressing any competing technological and market developments;
- the effects of any public health emergencies which may result in delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or foreign regulatory agencies to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our or our collaborators' clinical trials or the development of any of our product candidates. Even if one or more of our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and ongoing compliance efforts.

Even if we are able to generate revenue from the sale of any approved products, we may not become profitable, and we will need to obtain additional funding through one or more equity or debt financings in order to continue operations. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as large as we anticipate, the indication approved by regulatory authorities is narrower than we expect, the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines or the price and available third-party reimbursement are lower than anticipated, we may not generate significant revenue from sales of such product candidate, even if approved. 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 would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations and cause a decline in the value of our common stock, all or any of which may seriously harm our business.

We may encounter substantial delays in our clinical trials or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be initiated, conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of an IND or a clinical trial application ("CTA") will result in the FDA or other regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could delay, suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. In 2025, we initiated our wet AMD Phase 3 studies comparing a single dose of 4D-150 3E10 vg/eye to on-label aflibercept 2mg Q8 weeks. In September 2026, we initiated 4SIGHT, our Phase 3 clinical trial evaluating 4D-150 in treatment-naïve patients with DME. If we experience any delays in completing these trials, due to delays in enrollment or other factors, it could result in serious harm to our business. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory agencies on study design or implementation of the clinical trials;
- delays or failure in obtaining regulatory authorization to commence a trial;
- delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- refusal of the FDA to accept data from clinical trials in geographies outside the United States;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in identifying, recruiting, and enrolling patients who meet the requirements of our clinical trials;

- delays in obtaining required IRB approval or ethics committee opinion at each clinical trial site;
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment, CTA or amendment, or equivalent foreign application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; or a negative finding from an inspection of our clinical trial operations or study sites;
- developments on trials conducted by competitors for related technology that raise FDA or foreign regulatory authority concerns about risk to patients of the technology broadly; or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties, or us to adhere to clinical trial protocols;
- failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practice ("GCP") requirements or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance (including differing expectations across jurisdictions) that require amending or submitting new clinical protocols, expanding enrollment, modifying statistical assumptions (including non-inferiority margins), or submitting new or amended protocols, including for our Phase 3 trials of 4D-150;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a CDMO or by us, and delays or failure by our CDMOs or us to make any necessary changes to such manufacturing process;
- third parties being unwilling or unable to satisfy their contractual obligations to us; and
- adverse public perception or regulatory scrutiny of genetic medicine technology may negatively impact the developmental progress or commercial success of products that we develop alone or with collaborators.

Patient enrollment, a determinative factor in the timing of clinical trials, is affected by many factors including the severity and difficulty of diagnosing the disease under investigation, knowledge of the disease in the medical community and availability of effective diagnostic methods, size and distribution of the patient population and process for identifying subjects. Enrollment is also affected by access of patients to medical professionals experienced in their disease, our ability to effectively disseminate information about our clinical trials to the patient population and access of patients to such information, eligibility and exclusion criteria for the trial in question, design of the trial protocol, availability, efficacy of, and our ability to compete with approved and standard of care therapies or other clinical trials for the disease or condition under investigation, perceived risks and benefits of the product candidate under trial or testing, availability of genetic testing for potential patients, efforts to facilitate timely enrollment in clinical trials, patient referral practices of physicians, ability to obtain and maintain subject consent, the risk that enrolled subjects will drop out before completion of the trial, the ability to monitor patients adequately during and after treatment, the time and financial commitments required of patients to enroll in our trials beyond the costs we cover, and the proximity and availability of and access to clinical trial sites for prospective patients. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance.

Any inability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required, or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may seriously harm our business.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial 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 candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, 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 product candidates and could seriously harm our business.

The limited number of patients who have the diseases for which many of our product candidates are being studied may make it more difficult for us to enroll or complete clinical trials or may result in findings in our clinical trials that do not reach levels of statistical significance sufficient for marketing approval.

Many of the conditions for which we plan to evaluate our current product candidates in clinical trials are rare genetic diseases. Accordingly, there are limited patient pools from which to draw for clinical trials. In addition to the rarity of these diseases, the eligibility criteria of our clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure to assure their disease is either severe enough or not too advanced to include them in a trial. We or our collaborators may not be able to initiate or continue clinical trials on a timely basis or at all for any of our product candidates if we or our collaborators are unable to locate and enroll a sufficient number of eligible patients to participate in the trials as required by applicable regulations or as needed to provide appropriate statistical power for a given trial. Similarly, because many of the conditions we intend to treat are rare in nature, we plan to design and conduct clinical trials utilizing a small number of patients in order to evaluate the safety and therapeutic activity of our product candidates. Conducting trials in smaller subject populations increases the risk that any safety or efficacy issues observed in only a few patients could prevent such trials from reaching statistical significance or otherwise meeting their specified endpoints, which could require us to conduct additional clinical trials, or delay or prevent our product candidates from receiving regulatory approval, which would seriously harm our business.

Research and development of biopharmaceutical products is inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized or if they will ever be successfully commercialized.

Aside from 4D-150, our product candidates are at an early stage of development. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following:

- our product candidates may not successfully complete preclinical studies or clinical trials;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it does not meet applicable regulatory criteria;
- our competitors may develop therapeutics that render our product candidates obsolete or less attractive;
- our competitors may develop platform technologies that render our Therapeutic Vector Evolution platform technology obsolete or less attractive;
- the product candidates and Therapeutic Vector Evolution platform technology that we develop may not be sufficiently covered by intellectual property for which we hold exclusive rights or may be covered by third-party patents or other intellectual property or exclusive rights;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate;
- delays in our clinical development plans due to public health emergencies; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we or our collaborators may be forced to abandon our development efforts for a product candidate or candidates, which would seriously harm our business. Failure of a product candidate may occur at any stage of preclinical or clinical development, and, because most of our product candidates and our Therapeutic Vector Evolution platform technology are in an early stage of development, there is a relatively higher risk of failure, and we may never succeed in developing marketable products or generating product revenue.

We may not be successful in our efforts to further develop our Therapeutic Vector Evolution platform technology and current product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Aside from 4D-150, each of our product candidates is in the early stages of development and will require significant additional clinical development, management of preclinical, clinical, and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization, and significant marketing efforts before we generate any revenue from product sales, if at all. Any clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates or if we do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates.

If any of our product candidates successfully complete clinical trials, we generally plan to seek regulatory approval to market our product candidates in the United States, the EU, and in additional foreign countries where we believe there is a viable commercial opportunity. We have never commenced, compiled or submitted an application seeking regulatory approval to market any product candidate, which may impede our ability to secure approval and successfully launch our therapies. We may never receive regulatory approval to market any product candidates even if such product candidates successfully complete clinical trials, which would seriously harm our business. To obtain regulatory approval in countries outside the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, purity, potency, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. We may also rely on our collaborators or collaboration partners to conduct the required activities to support an application for regulatory approval, and to seek approval, for one or more of our product candidates. We cannot be sure that our collaborators or collaboration partners will conduct these activities successfully or do so within the timeframe we desire. Even if we (or our collaborators or collaboration partners) are successful in obtaining approval in one jurisdiction, we cannot assure you that we will obtain approval in any other jurisdictions. Failure to obtain approval for our product candidates in multiple jurisdictions will seriously harm our business.

Even if we receive regulatory approval to market any of our product candidates, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Any approval we may obtain could be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain approval. In addition, regulatory authorities may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a REMS. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would seriously harm our business.

Investment in biopharmaceutical product development involves significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot assure you that we will be able to successfully advance any of our product candidates through the development process or, if approved, successfully commercialize any of our product candidates.

Public health crises such as pandemics or similar outbreaks have affected and could continue to seriously and adversely affect our preclinical and clinical trials, business, financial condition and results of operations.

Public health crises, such as pandemics or similar outbreaks, could result in public health guidance measures, including in the locations of our offices, clinical trial sites, key vendors and partners. We expect that our clinical development program timelines could be negatively affected by such pandemics, any public health orders or measures implemented in response to such pandemics, or residual effects thereof, which could seriously harm our business.

Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations or policy changes 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.

The ability of the FDA and foreign regulatory authorities to review and/or approve new products can be affected by a variety of factors, including government budget, personnel, and funding levels, statutory, regulatory, and policy changes, the FDA's and foreign 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 foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, which have resulted in substantial personnel changes, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if funding shortages, staffing limitations, or policy changes prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, such events could significantly impact the ability of the FDA or such other regulatory authorities to timely review and process our regulatory submissions, which could seriously harm our business.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization, which could seriously harm our business.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we or our collaborators must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Further, because our product candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. We cannot be certain that our ongoing and planned clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could seriously harm our business.

Further, even if such clinical trials are successfully completed, we cannot assure you that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change, and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation ("CTR"), which was adopted in April 2014 and repealed the EU Clinical Trials Directive, became applicable on January 31, 2022, with a three-year transition period. The CTR provides for a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. As of February 1, 2025, all clinical trials (including those which are ongoing) in the EU are subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our development plans in the EU.

Interim, "top-line" and preliminary data from studies or trials that we announce or publish from time to time may change as more 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 publicly disclose top-line or preliminary data from 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 study or 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. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or "top-line" 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, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, top-line or interim data and final data could seriously harm our business.

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 product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what we determine to be material information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line or interim data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could seriously harm our business.

We may not be successful in our efforts to continue to create a pipeline of product candidates or to develop commercially successful products. If we fail to successfully identify and develop additional product candidates, our commercial opportunity may be limited, which could seriously harm our business.

One of our strategies is to identify and pursue preclinical and clinical development and commercialization of additional product candidates through our Therapeutic Vector Evolution platform technology. Our Therapeutic Vector Evolution platform technology may not produce a pipeline of viable product candidates, or our competitors may develop platform technologies that render our Therapeutic Vector Evolution platform technology obsolete or less attractive. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make them unmarketable or unlikely to receive marketing approval. Identifying, developing and obtaining regulatory approval and commercializing additional product candidates will require substantial funding and is prone to the risks of failure inherent in drug development. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunity may be limited, which could seriously harm our business.

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

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of the indications for which we have product candidates, including wet AMD, DME, GA and cystic fibrosis. Certain of our competitors have commercially approved products for the treatment of the diseases that we are pursuing or may pursue in the future, including Apellis Pharmaceuticals Inc., Astellas Pharma Inc., Regeneron Pharmaceuticals Inc., Roche and Vertex Pharmaceuticals Incorporated. These drugs are well established therapies and are widely accepted by physicians, patients and third-party payors, which may make it difficult to convince these parties to switch to our product candidates. Companies that we are aware are developing therapeutics in the retina and pulmonology disease areas include large companies with significant financial resources, such as AbbVie Inc., Astellas Pharma Inc., Eli Lilly and Company, Johnson & Johnson, Merck & Company Inc., Regeneron Pharmaceuticals Inc., Roche, Sanofi and Vertex Pharmaceuticals Incorporated, and biopharmaceutical companies such as Apellis Pharmaceuticals Inc., Arcturus Therapeutics Holdings Inc., EyePoint Inc., Kodiak Sciences Inc., Krystal Biotech Inc., Ocular Therapeutix Inc., Recode Therapeutics Inc., REGENXBIO Inc. and Sionna Therapeutics Inc. In addition to competition from other companies targeting retina and pulmonology, any products we may develop may also face competition from other types of therapies, such as gene-editing therapies and drug delivery devices.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our product candidates. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of retina and pulmonology indications, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing against competitors any product candidates we may develop.

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

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing and commercial support infrastructure to sell, or participate in sales activities with our collaborators for some of our product candidates if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

Factors that may inhibit our efforts to commercialize any approved product on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, compliance, customer service, medical affairs and other support personnel;
- our inability to recruit and build a commercial infrastructure;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved and our business would be seriously harmed.

Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in pivotal clinical trials and published in peer-reviewed journals;
- the potential and perceived advantages compared to alternative treatments;
- the ability to offer our products for sale at competitive prices;

- the ability to offer appropriate patient access programs, such as co-pay assistance;
- sufficient third-party coverage or reimbursement;
- the extent to which physicians recommend our products to their patients;
- convenience and ease of dosing and administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by FDA, EMA or other regulatory agencies;
- product labeling or product insert requirements of the FDA, EMA or other comparable foreign regulatory authorities, including any limitations, contraindications or warnings contained in a product's approved labeling;
- restrictions on how the product is distributed;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- the strength of marketing and distribution support; and
- the prevalence and severity of any side effects.

If any product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenue, and we may not become profitable and our business could be seriously harmed.

Risks Related to Manufacturing

Gene therapies are novel, complex and difficult to manufacture. We could experience production problems that result in delays in our development or commercialization programs, limit the supply of our products or otherwise seriously harm our business.

We currently manufacture and test clinical trial material for our products both internally at our cGMP facility, and externally at our partner CDMOs. Our product candidates require processing steps that are more complex than those required for most chemical and protein pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as ours generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, we employ multiple steps to control our manufacturing process to assure that the process works and the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory, which could delay or prevent the initiation of clinical trials or receipt of regulatory approvals. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs.

In addition, FDA and other comparable foreign regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA or other comparable foreign regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay clinical trials or product launches which could be costly to us and otherwise seriously harm our business.

We also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to operate our manufacturing process which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing process or the facilities with which we contract could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies, which could limit our access to additional attractive development programs. Problems in manufacturing processes or facilities also could restrict our ability to meet market demand for our products. Additionally, should our supply needs exceed our internal capabilities and supply agreements with other parties with whom we have manufacturing agreements be terminated for any reason, there are a limited number of manufacturers who would be suitable replacements, and it would take a significant amount of time to transition the manufacturing to an alternative manufacturing organization.

Delays in obtaining regulatory approval of our manufacturing process or disruptions in our manufacturing process may delay or disrupt our commercialization efforts.

Before we can begin to commercially manufacture our product candidates in third-party or our own facilities, we must obtain regulatory approval from the FDA to market our product using the manufacturing process and facility we proposed in our marketing application. In addition, we must successfully complete a pre-approval inspection of our manufacturing facility by the FDA before any of our product candidates can obtain marketing approval, if ever. In order to obtain approval of a Biologics License Application ("BLA") for our product candidates, we will need to ensure that all of our manufacturing processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any products that we may develop. Similar risks may exist in foreign jurisdictions.

Delays in developing our manufacturing capabilities or failure to achieve operating efficiencies from it may require us to devote additional resources and management time to manufacturing operations and may delay our product development timelines.

We have approximately 17,000 square feet of laboratory and manufacturing space at our headquarters in Emeryville, California, a large portion of which we plan to devote to manufacturing activities for our clinical trials under cGMP. We may face delays in the production of clinical supply at our manufacturing facility and cannot guarantee when our facility will be able to produce sufficient quantities of product candidates needed to support our planned clinical trials. Any delays in developing our internal manufacturing capabilities may disrupt or delay the supply of our product candidates if we have not maintained a sufficient back-up supply of such product candidates through third-party manufacturers. Moreover, changing manufacturing facilities during the clinical development process may also require that we or our collaborators conduct additional studies, make notifications to regulatory authorities, make additional filings to regulatory authorities, and obtain regulatory authority approval for the new facilities, which may be delayed or which we may never receive. We will further need to comply with the FDA's and applicable foreign regulatory authorities' cGMP requirements for the production of product candidates for clinical trials and, if approved, commercial supply, and will be subject to FDA and comparable foreign regulatory authority inspection. These requirements include the qualification and validation of our manufacturing equipment and processes. We may not be able to develop or acquire the internal expertise and resources necessary for compliance with these requirements.

In order to develop internal manufacturing expertise, we may be forced to devote greater resources and management time than anticipated, particularly in areas relating to operations, quality, regulatory, facilities and information technology. We also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to operate our manufacturing processes. If we experience unanticipated employee shortage or turnover in any of these areas, we may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate from developing these capabilities, which may negatively affect our product development timeline or result in difficulties in maintaining compliance with applicable regulatory requirements. Any such problems could result in the delay, prevention or impairment of clinical development and commercialization of our product candidates and would seriously harm our business.

We currently rely and expect to continue to rely on third parties to conduct product manufacturing for certain of our product candidates, and these third parties may not perform satisfactorily.

We currently rely, and expect to continue to rely, on third parties for the production of some of our planned clinical trial drugs and commercial drug materials and, therefore, we can control only certain aspects of their activities. The facilities used by our contract manufacturers to manufacture certain of our product candidates must be reviewed by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the cGMP or similar foreign requirements for manufacture of our products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to obtain and/or maintain regulatory approval for our products as manufactured at their manufacturing facilities. Further, our CDMOs may use different facilities to manufacture our product candidate(s), and we and our CDMOs will be required to meet certain regulatory conditions, such as establishing comparability between the product candidates manufactured at each facility. Our failure, or failure by our CDMOs, to demonstrate sufficient comparability between a product candidate manufactured at different facilities may cause a delay in using a manufacturing facility for production, extend our clinical trial timelines and adversely impact our regulatory approval process. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

In addition, we rely on additional third parties to manufacture plasmids used in the manufacture of our product candidates and to perform quality testing, and reliance on these third parties entails risks to which we would not be subject if we manufactured the plasmids ourselves, including:

- reduced control over certain aspects of manufacturing activities;
- termination or nonrenewal of manufacturing and service agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize future product candidates. Some of these events could be the basis for FDA or EU member state competent authority action, including injunction, recall, seizure or total or partial suspension of product manufacture.

Any contamination in our manufacturing process, shortages of raw materials or failure of any of our key suppliers to deliver necessary components could result in delays in our research studies, preclinical, and clinical development or marketing schedules.

Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and cause reputational damage.

Some of the raw materials required in our manufacturing process, such as plasmids, are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could seriously harm our business.

We depend on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could seriously harm our business.

We rely on third-party suppliers for the raw materials required for the production of our product candidates. Third-party suppliers could increase their prices or be unable to supply us with adequate raw materials, on a timely basis or at all, for a variety of reasons, including potential restrictions on trade or tariffs. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited, and we are likely to get lower priority than our competitors who are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any interruption in supply of raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supplier in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would seriously harm our business.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

The regulatory approval processes of the FDA, EMA and comparable foreign regulatory authorities are lengthy, expensive, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

We and any collaborators are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. We have not submitted for or obtained regulatory approval for any product candidate. We and any collaborators must complete additional preclinical or nonclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the regulatory authorities before we will be able to obtain these approvals, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our or our collaborators' clinical trials;
- the FDA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use of our products;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- we or our collaborators may be unable to demonstrate to the FDA, or comparable foreign regulatory authorities that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our or our collaborators' interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would seriously harm our business.

In addition, even if we or our collaborators were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a REMS. Regulatory authorities or other authorities responsible for pricing negotiations may not approve the price we or our collaborators intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We may in the future seek an accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product 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, confirmatory studies to verify and describe the drug's clinical benefit. If such confirmatory studies fail to confirm the drug's clinical benefit, or if the sponsor fails to conduct required confirmatory studies in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, in December 2022, the Food and Drug Omnibus Reform Act of 2022 provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval for any of our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA 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. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Even if we or our collaborators obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

If one of our product candidates is approved, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations or similar foreign requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP or similar foreign requirements and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products "off-label" for indications or uses for which they do not have approval, though we may share truthful and not misleading information that is otherwise consistent with our product's approved labeling. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval or label restrictions.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our manufacturing facility or our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business will be seriously harmed.

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

We have received orphan drug designation for 4D-710 for cystic fibrosis, and we may seek orphan drug designation for certain future product candidates. However, we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

We have received orphan drug designation in the United States for 4D-710 for the treatment of cystic fibrosis. Although we may seek orphan product designation for some or all of our other product candidates, we may never receive such designations. Under the Orphan Drug Act, the FDA may designate a drug or biologic product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 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. Orphan drug designation must be requested before submitting a BLA. Orphan designation is granted by the European Commission ("EC") based on a scientific opinion of the EMA's Committee for Orphan Medicinal Products ("COMP"). A medicinal product may be designated as orphan if its sponsor can establish that (i) the product is intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the medicinal product will be of significant benefit to those affected by the condition. The application for orphan designation must be submitted before the application for marketing authorization.

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 application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

In addition, if a product receives the first FDA approval for the disease or condition for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same approved use or indication within such rare disease or condition for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for a disease or condition broader than the orphan designated disease or condition and may be lost if the FDA later determines that the request for designation was materially defective. In the EU, orphan designation entitles a party to financial incentives such as reduction of fees, fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Moreover, upon grant of a marketing authorization and assuming the requirements for orphan designation are also met at the time the marketing authorization is granted, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan ("PIP"). The European exclusivity period can be reduced to six years, if, at the end of the fifth year a medicine no longer meets the criteria for orphan designation (i.e. the prevalence of the condition has increased above the orphan designation threshold or it is judged that the product is sufficiently profitable so as not to justify maintenance of market exclusivity).

Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same uses or indications within the same rare disease or condition. Even after an orphan drug is approved, the FDA and foreign regulatory authorities can subsequently approve the same drug for the same approved use or indication within the same rare disease or condition if the FDA or foreign regulatory authorities conclude that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process.

We have received Regenerative Medicine Advanced Therapy ("RMAT") and PRIority MEdicines ("PRIME") designation for 4D-150 for the treatment of wet AMD and RMAT designation for 4D-150 for treatment of DME. We may seek RMAT and PRIME designations for certain future product candidates, however we may not be able to obtain such designations, and there is no guarantee that 4D-150 will experience a faster regulatory review or obtain regulatory approval.

The FDA has granted RMAT designation for 4D-150 for the treatment of neovascular (wet) age-related macular degeneration and diabetic macular edema, and may seek additional RMAT designations for 4D-150 or for our other product candidates. A biological product candidate is eligible for RMAT designation if: (1) it meets the definition of a regenerative medicine therapy, which the FDA defines as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) the candidate is intended to treat, modify, reverse, or cure a serious disease or condition; and (3) preliminary clinical evidence indicates that the candidate has the potential to address unmet medical needs for such disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review of BLAs. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or through reliance upon data obtained from a meaningful number of sites, including through expansion of clinical trials to a sufficient number of sites, as appropriate. RMAT-designated product candidates that receive accelerated approval may, as appropriate, be able to fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence (such as electronic health records), through the collection of larger confirmatory data sets, or via post-approval monitoring of patients treated with the therapy prior to approval.

RMAT designation is within the sole discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for RMAT designation, the FDA may disagree and instead determine not to make such designation. RMAT designation does not change the standards for product approval, and there is no assurance that such designation or eligibility for such designation will result in expedited review or approval, or that the approved indication will not be narrower than the indication covered by the RMAT designation.

In the EU, 4D-150 was accepted into the PRIME scheme by the EMA's Committee for Medicinal Products for Human Use ("CHMP") for the treatment of wet AMD. In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which was launched by the EMA in 2016 and provides incentives similar to the Breakthrough Therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target an unmet medical need. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. The benefits of a PRIME designation include the appointment of a rapporteur before submission of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

Product developers that benefit from PRIME designation may be eligible for accelerated assessment (in 150 days instead of 210 days), which may be granted for medicinal products of major interest from a public health perspective or that target an unmet medical need, but this is not guaranteed.

Receipt of these designations does not increase the likelihood that FDA or EC will approve 4D-150 for any indication. In addition, the FDA or foreign competent authorities may rescind the designations if they believe that the designation is no longer supported by data from our clinical development program.

We have obtained a rare pediatric disease designation for 4D-710, however, there is no guarantee that FDA approval of 4D-710 will result in issuance of a priority review voucher.

In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" that meets certain criteria may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

We have obtained a rare pediatric disease designation for 4D-710 for the treatment of cystic fibrosis, however, there is no guarantee that we will be able to obtain a priority review voucher, even if 4D-710 is approved by the FDA for this indication. For example, the FDA may determine that a BLA, even if ultimately approved, does not meet the eligibility criteria for a priority review voucher, including for the following reasons:

- the product no longer meets the definition of a rare pediatric disease;
- the product contains an active ingredient (including any ester or salt of the active ingredient) that has been previously approved in another marketing application;
- the application does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population; and
- the application is approved for a different adult indication than the rare pediatric disease for which the product is designated.

Moreover, Congress included a sunset provision in the statute authorizing the rare pediatric disease priority review voucher program. Under the current statutory sunset provisions, FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for the product candidate, and the product candidate is approved within the designated rare pediatric disease by September 30, 2029. After September 30, 2029, FDA may not award vouchers under the program, regardless of any designation.

If the product candidates that we or our collaborators may develop receive regulatory approval in the United States or another jurisdiction, they may never receive approval in other jurisdictions, which would limit market opportunities for such product candidates and seriously harm our business.

Approval of a product candidate in the United States by the FDA or by the requisite regulatory agencies in any other jurisdiction does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions. The approval process varies among countries and may limit our or our collaborators' ability to develop, manufacture, promote and sell product candidates internationally. Failure to obtain marketing approval in international jurisdictions would prevent the product candidates from being marketed outside of the jurisdictions in which regulatory approvals have been received. In order to market and sell product candidates in the EU and many other jurisdictions, we and our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional preclinical studies or clinical trials both before and after approval. In many countries, any product candidate for human use must be approved for reimbursement before it can be approved for sale in that country. In some cases, the intended price for such product is also subject to approval. Further, while regulatory approval of a product candidate in one country does not ensure approval in any other country, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we or our collaborators fail to comply with the regulatory requirements in international markets or to obtain all required marketing approvals, the target market for a particular potential product will be reduced, which would limit our ability to realize the full market potential for the product and seriously harm our business.

Enacted and future healthcare legislation or regulation may increase the difficulty and cost for us to obtain marketing approval of and to commercialize our product candidates and may affect the prices we may set.

In the United States, the EU and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could, among other things, restrict our ability to profitably sell our product candidates and could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States and elsewhere, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative and regulatory initiatives. We expect that current laws, 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 may receive for any product candidates approved for sale. New and changing laws and regulations may also create uncertainty about how such laws and regulations will be interpreted and applied. If we are found to have violated laws and regulations, it could materially adversely affect our business, results of operations and financial condition.

For example, in 2010, the Patient Protection and Affordable Care Act (the "ACA") was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA of importance to our business, including, without limitation, our ability to commercialize and to obtain adequate prices for any product candidates approved for sale, are the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;

- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs, revising the "average manufacturer price" definition, and extending rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; and
- establishment of a Center for Medicare & Medicaid Innovation ("CMMI") at the Centers for Medicare & Medicaid Services ("CMS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, U.S. Congressional and executive branch challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on drug manufacturers' Medicaid drug rebate program liability for single source and innovator multiple source drugs, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

In 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discount program (beginning in 2025). CMS has published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs, which will first be effective in 2027, as well as the next set of 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the Department of Health and Human Services ("HHS") to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any other product candidate that we commercialize.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump administration's proposals will be implemented, the Trump administration's policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our product candidates, if approved. On the one hand, the Trump administration threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers entered into confidential pricing agreements with the federal government. Subsequently, in April 2026, the Trump administration issued a proclamation imposing tariffs under Section 232 of the Trade Expansion Act on imports of brand pharmaceuticals, biologics and associated pharmaceutical ingredients, beginning July 31, 2026. Exempted from these tariffs, among others, are companies that have executed or are negotiating agreements with the federal government regarding most favored nation pricing and onshoring of production and research and development. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, although final regulations have not yet been published. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient assistance programs. We also expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures and could seriously harm our business.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price reporting and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, while some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries. Legally mandated price controls on payment amounts by third-party payors or other restrictions could seriously harm our business. 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. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. Prescription drugs and biological products that are in violation of these requirements will be included on a public list. These reforms could reduce the ultimate demand for our product candidates or put pressure on our product pricing and could seriously harm our business.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage and payment criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. We cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or judicial action in the United States, the EU or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

The successful commercialization of any product candidates for which we obtain approval will depend in part on the extent to which governmental authorities, private health insurers, and other third-party payors provide coverage and adequate reimbursement. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if any and if approved, could limit our ability to market those products and decrease our ability to generate revenue.

Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

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

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs ("VA") hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if approved. Increasingly, other 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. For genetic medicine and other products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, that the level of reimbursement will be sufficient.

Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the medicine is approved by the FDA, EMA or other comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could seriously harm our business.

Even if we obtain FDA approval for any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell any products effectively, if approved, or generate product revenue.

We currently do not have a marketing or sales organization. In order to commercialize any product, if approved, in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In advance of any of our product candidates receiving regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such product candidate, which will be expensive and time-consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are not successful in commercializing products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses and our business would be seriously harmed.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties and seriously harm our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. 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;
- the U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil federal False Claims Act, which can be enforced through civil whistleblower or *qui tam* actions, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;

- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (as defined by statute), certain other non-physician practitioners (including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants, and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and
- similar healthcare laws in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

We may also be subject to additional federal laws, such as the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof, and federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

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, including certain of our advisory board arrangements with physicians, some of whom are compensated in the form of stock or stock options, 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 civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are 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, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant 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.

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

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

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our products.

The Animal Welfare Act ("AWA") is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and/or obligations exist in many foreign jurisdictions. If we or our contractors fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

Risks Related to Our Reliance on Third Parties

We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely and expect to continue to rely on third parties, such as CROs, CDMOs, clinical data management organizations, clinical data assessments and analysis organizations, medical institutions and clinical investigators, to conduct some aspects of our manufacturing, research, preclinical testing and clinical trials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities, but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register ongoing clinical trials and to post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Similar risks may exist in foreign jurisdictions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to manufacture, store and distribute drug supplies for our clinical trials. Any performance failure on the part of our manufacturers or distributors could delay clinical development, marketing approval or commercialization of any product candidates, producing additional losses and depriving us of potential product revenue.

We may depend on collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to realize the market potential of those product candidates.

We have sought, and may in the future seek, third-party collaborators for the research, development and commercialization of certain product candidates we may develop. Our likely collaborators for any other collaboration arrangements include large and mid-size pharmaceutical companies, regional, national and international pharmaceutical companies, biotechnology companies and academic institutions. If we enter into any such arrangements with any third parties, we will likely have shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop with them. Our ability to generate revenue from these arrangements with commercial entities will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our product candidates we may develop, pose the following risks to us:

- collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property;
- collaborators may own or co-own intellectual property covering our product candidates that result from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to collaborations;
- we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborators may decide not to pursue development and commercialization of any product candidates we 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 clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates 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 with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborators may undergo a change of control and the new owners may decide to take the collaboration in a direction which is not in our best interest;
- collaborators may become party to a business combination transaction and the continued pursuit and emphasis on our development or commercialization program by the resulting entity under our existing collaboration could be delayed, diminished or terminated;
- collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, devices, materials, know-how or intellectual property of the collaborator relating to our products and product candidates;
- key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators;
- collaborations may require us to incur short and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates or our Therapeutic Vector Evolution platform technology; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

We may face significant competition in seeking appropriate collaborations. Recent business combinations among biotechnology and pharmaceutical companies have resulted in a reduced number of potential collaborators. In addition, the negotiation process is time-consuming and complex, and we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate or delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue which could seriously harm our business.

If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elect not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations and company culture. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. We may also 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. Any collaborator may also be subject to many of the risks relating to product development, regulatory approval, and commercialization described in this "Risk Factors" section, and any negative impact on our collaborators may adversely affect us.

Our reliance on Chinese biotechnology companies may subject us to additional risks.

Certain Chinese biotechnology companies, CROs and contract development and manufacturing organizations may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which could potentially impact services available for our research and development or our ability to secure the materials we need for our product candidates. For example, the U.S. BIOSECURE Act, which was enacted in December 2025, prohibits federal agencies from procuring or using any biotechnology equipment or services from "biotechnology companies of concern", or entering into, extending, or renewing any contracts with entities that use such biotechnology equipment or services from "biotechnology companies of concern". Congress has interpreted a "biotechnology company of concern" as an entity that is under the control of a foreign adversary and that poses a risk to national security based on its research or multiomic data collection (e.g., collection of genomic information). While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts, and has carveouts for manufacture of drugs for supply under Medicaid and Medicare Part B, subject to the Secretary of Veteran Affairs' discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain. If the Chinese or other foreign CROs and CDMOs we rely on become subject to trade restrictions, sanctions, increased tariffs or other regulatory requirements by the U.S. government (including designation as a "biotechnology company of concern" under the U.S. BIOSECURE Act), or if the U.S. or Chinese government take retaliatory actions due to recent or increased tensions between the U.S. and China, it may have the potential to severely restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain "biotechnology companies of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. It is possible that some of our contractual counterparties could be impacted by the legislation described above. Such counterparties may be subject to U.S. legislation, 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 or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. Such disruption could have adverse effects on the development of our product candidates.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. Further, our licensed patents and applications include six granted patents (U.S. patent nos. 12,630,805, 12,310,997, 12,180,254, 11,136,557, 11,634,691 and 10,988,519) and two pending patent applications (U.S. patent application nos. 19/652,446 and 18/924,426), that were made with government support, that may be subject, under certain circumstances, to march-in-rights under 35 U.S.C. 203, which is a right that allows the government, in certain limited circumstances, to force a party with a license to intellectual property funded, at least in part, by the government, to grant a license to such property to another entity. U.S. patent nos. 11,136,557 and 11,634,691 were made with the support of U.C. Berkeley and relate to our A101 vector of our 4D-710 and 4D-725 product candidates. U.S. patent nos. 10,988,519 and 12,180,254 were made with the support of University of Pennsylvania and relate to our short-form human complement factor H (sCFH) payload of our 4D-175 product candidate. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our product candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could seriously harm our business.

We and our licensors have applied, and we intend to continue applying, for patents covering aspects of our product candidates, proprietary technologies and their uses that we deem appropriate. However, we may not be able to apply for patents on certain aspects of our current or future product candidates, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators or licensors will be successful in protecting our product candidates, proprietary technologies and their uses by obtaining and defending patents. These risks and uncertainties include the following:

- the U.S. Patent and Trademark Office (“USPTO”) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;
- other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position;
- any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or product candidates that we may develop;
- because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates, proprietary technologies and their uses;
- an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our licensors' patent applications for any patent application with an effective filing date before March 16, 2013;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute 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 before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. Moreover, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents, if issued, patents obtained by our collaborators or the patent rights that we license from others, may be challenged in the courts or patent offices in the United States and abroad. Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products or product candidates, or limit the duration of the patent protection of our product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such 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.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our product candidates are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our product candidates, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell, or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license;
- we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we or our licensors were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;
- we or our licensors were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe the patents we own or license;
- any of the patents we own or license will be found to ultimately be valid and enforceable;
- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable products or will provide us with any competitive advantages;

- a third party may not challenge the patents we own or license and, if challenged, a court would hold that such patents are valid, enforceable and infringed;
- we may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business;
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

Where we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could seriously harm our business.

Furthermore, our owned and in-licensed intellectual property rights may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could seriously harm our business.

The lives of our patents may not be sufficient to effectively protect our product candidates and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, are limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent life has expired, we may be open to competition. In addition, although upon issuance in the United States a patent's life can be extended based on certain delays caused by the USPTO and clinical development, this extension can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we do not have sufficient patent life to protect our product candidates, proprietary technologies and their uses, our business would be seriously harmed.

If we do not obtain patent term extension for our product candidates, our business may be seriously harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of any of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the 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 and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, 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. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration of the applicable product, and our business may be seriously harmed.

Changes in patent law in the United States or in other countries could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Our patent rights may be affected by developments or uncertainty in the U.S. or foreign patent statutes, patent case laws, USPTO rules and regulations or in the rules and regulations of foreign patent offices.

On September 16, 2011, the Leahy-Smith America Invents Act ("Leahy-Smith Act") was signed into law. There remains many subsisting issued patents and some pending patent applications in the U.S. that were filed prior to its enactment and are therefore subject to the pre-Leahy-Smith Act U.S. patent laws and that may have relevance to our freedom-to-operate or ability to obtain patent issuances. The Leahy-Smith Act includes a number of significant changes to the U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings including opposition, derivation, reexamination, inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. This could have a negative impact on some of our intellectual property and could increase uncertainties surrounding obtaining and enforcement or defense of our issued patents. In addition, Congress may pass patent reform legislation that is unfavorable to us. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future. Similarly, statutory or judicial changes to the patent laws of other countries may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

Additionally, on June 1, 2023, the European Union Patent Package (EU Patent Package) regulations were implemented with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (UPC) for litigation involving European patents. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. Thus far, we have elected to opt all of our European patents out of jurisdiction of the UPC, and we may elect to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain a pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

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

Filing, prosecuting and defending all current and future patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our 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. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Moreover, geo-political actions in the U.S. and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the U.S. and foreign government actions related to Russia's conflict with Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. For example, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the U.S. without consent or compensation. Consequently, we may not be able to prevent third parties from practicing our 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. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our product candidates and our patents or other IP rights may not be effective or sufficient to prevent them from competing.

The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents 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 may not prevail in any lawsuits that we initiate, and 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. 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 business may be seriously harmed.

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

Our agreements with employees and consultants provide that any inventions conceived by an individual in the course of rendering services to us shall be our exclusive property. Although our policy is to have all such individuals complete these agreements, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property may not be self-executing and despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. We may also be subject to claims that former employees, consultants, or other third parties have an ownership interest in our patents or other intellectual property. In addition, we may face claims by third parties that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could seriously harm our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to our management and other employees.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and if we license intellectual property we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. There could also be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the U.S. Department of Government Efficiency or other executive actions to reduce the size of the U.S. government.

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

We rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. We have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees and consultants. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and 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. In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant or third party with authorized access. Our security measures may not prevent an employee, consultant, collaborator or third party from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our product candidates that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Further, we may need to share our trade secrets and confidential know-how with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or actors in other countries, and those affiliated with or controlled by state actors.

Though our agreements with third parties typically restrict the ability of our employees, collaborators, licensors, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we have relied on, and in future expect to rely on third parties in the development, manufacture, and distribution of our product candidates and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of licenses granted to us by others, and the patent protection, prosecution and enforcement for some of our product candidates may be dependent on our licensors.

We currently are reliant upon licenses of certain patent rights and proprietary technology from third parties that are important or necessary to the development of our technology, including technology related to our product candidates. For example, we rely on our exclusive license agreements with (i) U.C. Berkeley for certain rights with respect to the intellectual property covering certain compositions of matter and methods of use of certain AAV variants related to our 4D-710 and 4D-725 product candidates, and (ii) University of Pennsylvania for certain rights with respect to the intellectual property covering certain compositions of matter and methods of use of the short-form human complement factor H (sCFH) payload related to our 4D-175 product candidate. These and other licenses we may enter into in the future may not provide adequate rights to use such intellectual property and technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. As a result, we may not be able to develop and commercialize our technology and product candidates in fields of use and territories for which we are not granted rights pursuant to such licenses.

Licenses to additional third-party technology that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms, which could seriously harm our business.

In some circumstances, we may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering technology that we license from third parties. In addition, some of our agreements with our licensors require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our product candidates. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

Our current licenses, and our future licenses, likely will impose various royalty payments, milestones, and other obligations on us. If we fail to comply with any of these obligations, we may be required to pay damages and the licensor may have the right to terminate the license. Termination by the licensor would cause us to lose valuable rights, and could prevent us from developing and commercializing our product candidates and proprietary technologies. Our business would be seriously harmed if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any current or future licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of royalty obligations we would be required to pay on the sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in product candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize any product candidates, we may be unable to achieve or maintain profitability.

If our trademarks and trade names, whether registered in the future or unregistered now, 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.

Any trademarks we may register in the future or any current registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. 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 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 trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. 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. We may license our trademarks and trade names, to the extent any are registered, to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could seriously harm our business.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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 genetic medicine products that are similar to our product candidates or utilize similar genetic medicine technology but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;

- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of 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 pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could seriously harm our business.

Our existing collaborations and any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Our existing collaborations, such as our collaboration with Otsuka Pharmaceutical Co., Ltd. and any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products and product candidates that compete directly or indirectly with our product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products and product candidates may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may adversely affect the price of our common stock and may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;

- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

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

Reliance on third parties to conduct clinical trials, assist in research and development and to manufacture our product candidates, will at times require us to share trade secrets with them. We seek to protect our proprietary technology by in part entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing 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, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may seriously harm our business.

We may fail to comply with any of our obligations under existing or future agreements pursuant to which we license or have otherwise acquired intellectual property rights or technology, which could result in the loss of rights or technology that are material to our business.

We are party to various agreements that we depend on to operate our business. Our rights to use currently licensed intellectual property, or intellectual property to be licensed in the future, are or will be subject to the continuation of and our compliance with the terms of these agreements. These agreements are complex, and certain provisions in such agreements may be susceptible to multiple interpretations which could lead to disputes, including but not limited to those regarding:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our proprietary technology and product candidates infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the creation or use of intellectual property by us or our counterparties, alone or jointly;
- the scope and duration of our payment obligations;
- rights upon termination of such agreement; and
- the scope and duration of exclusivity obligations of each party to the agreement.

The resolution of any contractual interpretation dispute that may arise, if unfavorable to us, could seriously harm our business. Such resolution could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement, or decrease the third party's financial or other obligations under the relevant agreement.

If disputes over intellectual property rights that we have licensed or acquired from third parties prevent or impair our ability to maintain our current license agreements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we fail to comply with our obligations under current or future license agreements, these agreements may be terminated or the scope of our rights under them may be reduced and we might be unable to develop, manufacture or market any product that is licensed under these agreements.

Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents or other proprietary rights of third parties.

Third parties may have or obtain patents or other proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and future approved products, if any, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexaminations, inter partes review proceedings and post-grant review proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. Further, we may incorrectly determine that our technologies or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates.

As the biotechnology industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. patent applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our product candidates. As a result, we may be unaware of third-party patents that may be infringed by commercialization of our product candidates, and cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; and/or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all.

Although no third party has asserted a claim of patent infringement against us as of the date of this report, others may hold proprietary rights that could prevent our product candidates or any future products from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates or proprietary technologies could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates or any future products. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be time-consuming and a substantial diversion of management and employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins, and the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. In addition, we cannot be certain that we could redesign our product candidates or proprietary technologies to avoid infringement, if necessary, or on a cost-effective basis. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates or any future products which could seriously harm our business. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. Also, we may be obligated under our agreements with our collaborators, licensors, suppliers and others to indemnify and hold them harmless for damages arising from intellectual property infringement by us.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged.

Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court or administrative tribunal may decide that a patent we own or license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in foreign patent offices and may result in the revocation, cancellation, or amendment of any foreign patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on an affected product candidate. Such a loss of patent protection would seriously harm our business.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO, or equivalent actions brought in foreign jurisdictions, may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be seriously harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights 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 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace and seriously harm our business.

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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and licenses.

We currently have rights to the intellectual property, through licenses from third parties and under patents that we own, to develop our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will depend in part on our ability to acquire, license or use these proprietary rights. We may be unable to acquire or license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These 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. 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.

We have collaborated with a U.S. academic institution and may in the future collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license 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 other parties, potentially blocking our ability to pursue our program.

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 that program and our business could be seriously harmed.

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

As is common in the biotechnology and biopharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. 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 biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, 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. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees or consultants, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer or former or current client. 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, which could seriously harm 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 and other employees.

Risks Related to Our Operations

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. The loss of the services provided by any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business.

We conduct our operations at our facilities in Emeryville, California, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we may need to recruit talent from outside of our region, and doing so may be costly and difficult.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity grants. The value to employees of these equity grants 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. In addition, our employees are employed at-will, which means that any of our employees could leave our employment at any time, with or without notice. If we are unable to attract, incentivize and retain quality personnel on acceptable terms, or at all, it could seriously harm our business.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As our development plans and strategies evolve, we must add a significant number of additional managerial, operational, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our current and future product candidates, while complying with our contractual obligations to contractors and other third parties;
- expanding our operational, financial and management controls, reporting systems and procedures; and
- managing increasing operational and managerial complexity.

Our future financial performance and our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to manage these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from factors such as increased inflation or closure of or liquidity issues at financial institutions or other macro factors such as a pandemic or geopolitical tensions could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Our information technology systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches and other disruptions.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, clinical trial data, proprietary business information and personal information of our employees and contractors (collectively, "Confidential Information"). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. Despite the implementation of security measures, our internal information technology systems and those of our collaborators, CROs and other contractors and consultants may be vulnerable to attack, damage and interruption from computer viruses and malware (e.g. ransomware), malicious code, misconfigurations, "bugs" or other vulnerabilities, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, denial or degradation of service attacks, and sophisticated nation-state and nation-state supported actors.

The risk of a security breach or disruption, particularly through cyberattacks 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 and our third party service providers and partners may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques, including artificial intelligence, that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Our third party service providers and partners are also subject to these heightened risks. The costs to us to investigate and mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, negative publicity and other harm to our business and our competitive position. There can also be no assurance that our and our collaborators', future CROs' and other contractors' and consultants' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

We and certain of our service providers have experienced certain cyberattacks and security incidents from time to time. Although to our knowledge we have not experienced any significant system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our Confidential Information or other similar disruptions. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of clinical trial data or personal data, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media, and other parties pursuant to privacy and security laws.

Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their information technology systems could also seriously harm our business. Any security compromise affecting us, our partners or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures, and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of Confidential Information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed. Any losses, costs or liabilities may not be covered by, or may exceed the coverage limits of, any applicable insurance policies.

Furthermore, federal, state and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, if our information technology security efforts fail. Any adverse impact to the availability, integrity or confidentiality of our or third-party systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. We may also be exposed to a risk of loss or litigation and potential liability, which could materially and adversely affect our business, results of operations or financial condition.

Business disruptions could seriously harm our business.

Our operations, and those of our CROs, CDMOs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are partly uninsured. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our business.

All of our operations including our corporate headquarters are located in multiple facilities in Emeryville, California. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, earthquake and other natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business could be seriously harmed by such delays and interruption.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data, such as information that we may collect in connection with clinical trials in the United States and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could seriously harm our business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder (collectively, “HIPAA”), imposes, among other things, certain standards on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the "CCPA") requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Similar laws have passed in other states, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Furthermore, in 2024, the National Security Division of the U.S. Department of Justice ("DOJ") issued a new rule—referred to as the "Data Security Program" ("DSP")—to implement Executive Order 14117 aimed at preventing access to "bulk U.S. sensitive personal data" and "government-related data" by "countries of concern" (including China, Russia, Iran, North Korea, Cuba, and Venezuela) and "covered persons" (as all such terms are defined in the DSP). Effective as of April 8, 2025, and fully enforceable as of July 9, 2025, the DSP imposes stringent obligations on companies within its scope and prohibits or restricts "covered data transactions" that grant countries of concern or covered persons access to bulk U.S. sensitive personal data or any amount of government-related data. The DSP is new, complex and has yet to be enforced, and as such, there is a risk that our interpretation of its applicability, scope, and requirements is incorrect, incomplete, or misapplied. Compliance with the DSP may require us to invest heavily in data security and compliance measures, such as implementing and complying with the Cybersecurity and Infrastructure Security Agency's guidelines and other burdensome recordkeeping, reporting, and auditing requirements. It may also require us to implement new processes, stop or restrict certain data transfers, alter the geographic scope of our operations, cease doing business with certain third parties or using certain tools or vendors, or change how data flows throughout our business, any of which could materially impact our business operations or hinder our ability to grow our business. Finally, non-compliance with the DSP could result in significant civil or criminal penalties, which could materially adversely affect our business, results of operations, and financial condition.

In Europe, the European Union General Data Protection Regulation (the "EU GDPR") and the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the "UK GDPR") (the EU GDPR and UK GDPR together referred to as the "GDPR") impose strict requirements for processing the personal data of individuals within the European Economic Area ("EEA") and in the United Kingdom, respectively. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million / £17.5 million or 4% of the annual global revenue of the noncompliant undertaking, whichever is greater. Since we are subject to the supervision of relevant data protection authorities under multiple legal regimes (including under both the EU GDPR and the UK GDPR), we could be fined under each of those regimes independently in respect of the same breach. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease or change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/or civil claims (including class actions). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. Case law from the Court of Justice of the European Union ("CJEU") states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we operate our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Additionally, the Securities and Exchange Commission (the "SEC") has adopted rules that enhance and standardize disclosures regarding cybersecurity risk management, strategy, and governance, as well as material cybersecurity incidents. Under these rules, we are required to make annual disclosures describing our processes for assessing, identifying and managing material risks from cybersecurity threats, management's role in assessing and managing such risks and our board of directors' oversight of risks from cybersecurity threats. We are also required to disclose, in a Current Report on Form 8-K, the material aspects of the nature, scope and timing of any material cybersecurity incident and its material impact or reasonably likely material impact on us.

As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and seriously harm our business.

Our business may be affected by the evolving regulatory framework for AI Technologies.

We use artificial intelligence ("AI"), machine learning, and automated decision-making technologies, (collectively, "AI Technologies") in our business. We expect that increased investment will be required in the future to continuously improve our use of AI Technologies. As with many technological innovations, there are significant risks involved in developing, maintaining and deploying these technologies, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging technologies increases regulatory, cybersecurity and other significant risks. There can be no assurance that the usage of or our investments in such technologies will always enhance our products or services or be beneficial to our business, including our efficiency or profitability.

In particular, if the models underlying our AI Technologies are: incorrectly designed or implemented; trained or reliant on incomplete, inadequate, inaccurate, biased or otherwise poor quality data, or on data to which we do not have sufficient rights or in relation to which we and/or the providers of such data have not implemented sufficient legal compliance measures; used without sufficient oversight and governance to ensure their responsible use; and/or adversely impacted by unforeseen defects, technical challenges, cybersecurity threats or material performance issues, the performance of our products, services and business, as well as our reputation, could suffer or we could incur liability resulting from the violation of laws or contracts to which we are a party or civil claims.

We are in varying stages of development in relation to our products and internal business processes involving AI Technologies. The continuous development, maintenance and operation of our AI Technologies is expensive and complex, and may involve unforeseen difficulties including material performance problems, undetected defects or errors. For instance, the models underlying AI Technologies can experience decay (also known as "model drift") in which its performance and accuracy decreases over time without further human intervention to correct such decay.

We may not be successful in our ongoing development and maintenance of these technologies in the face of novel and evolving technical, reputational and market factors. Our efforts to develop proprietary AI Technologies could increase our operating costs. Our ability to develop proprietary AI Technologies may be limited by our access to processing infrastructure or training data, and we may be dependent on third-party providers for such resources.

The regulatory framework for AI Technologies is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect the operation of our AI Technologies. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or market perception of their requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations. Failure to appropriately respond to this evolving landscape may result in reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

It is possible that new laws and regulations will be adopted in the U.S. and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our products, services, and business and the way in which we use AI Technologies. We may need to expend resources to adjust our products or services in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

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

Under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change" (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards ("NOLs") and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. If finalized, Treasury Regulations currently proposed under Section 382 of the Code may further limit our ability to utilize our pre-change NOLs or other pre-change tax attributes if we undergo a future ownership change. We have experienced ownership changes in the past. We may also experience ownership changes as a result of any future shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our NOLs and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation. We will be unable to use our NOLs or other tax attributes if we do not attain profitability sufficient to offset our available NOLs or other tax attributes prior to their expiration, to the extent subject to expiration.

Changes in tax laws or regulations that are applied adversely to us or our customers may seriously harm our business.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of any of our future domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be volatile, which could result in substantial losses for investors.

Some of the factors that may cause the market price of our common stock to fluctuate include:

- results from, and any delays in, our clinical trials for our clinical-stage product candidates or any other future clinical development programs;
- the success of existing or new competitive products or technologies;
- commencement or termination of collaborations for our product candidates;
- failure or discontinuation of any of our product candidates;
- failure to develop our Therapeutic Vector Evolution platform technology;
- results of preclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- regulatory or legal developments in the United States and other countries, including sanctions imposed by either the U.S. or foreign governments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the commencement of litigation;
- the level of expenses related to any of the research programs or product candidates that we may develop;

- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- the impact of political instability, natural disasters, war and/or events of terrorism, such as the war between Ukraine and Russia, and the corresponding tensions created from such conflict between Russia, the United States and countries in Europe as well as other countries such as China, and the ongoing war in the Middle East;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions; and
- the other factors described in this “Risk Factors” section.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Further, the stock market in general has been highly volatile due to macroeconomic factors such as higher inflation and increased interest rates and political uncertainty in the United States. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Since the completion of our initial public offering in December 2020, the price of our common stock has been volatile, and we expect such volatility to continue. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management’s attention and resources from our business.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of these analysts should drop research coverage of us or if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares of our common stock intend to sell shares, could reduce the market price of our common stock.

Further, shares issued upon the exercise of stock options outstanding under our equity incentive plans, or pursuant to future awards granted under those plans, will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules and Rule 144 and Rule 701 under the Securities Act.

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

We will seek additional capital through one or a combination of public and private equity offerings, debt financings, strategic partnerships and alliances, licensing arrangements, and the term loans under our Loan Agreement with Hercules. We, and indirectly, our stockholders, will bear the cost of issuing and servicing such securities. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future offerings. To the extent that we raise additional capital through the sale of equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

Additionally, as of September 30, 2026, there are Pre-funded Warrants outstanding to purchase 16,004,945 shares of common stock, which are exercisable at a nominal exercise price. If holders of these Pre-funded Warrants exercise these securities, existing stockholders will suffer dilution to their voting power and we may experience dilution in our earnings per share, as well as a negative impact on our share price.

Insiders have substantial influence over us, which could limit your ability to affect the outcome of key transactions, including a change of control.

Our directors, executive officers, holders of more than 5% of our outstanding stock and their respective affiliates beneficially own shares representing approximately 62% of our outstanding common stock as of September 30, 2026. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

We incur significant costs as a result of operating as a public company, and our management devotes substantial time to public company compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would seriously harm our business.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Select Market and the rules of the SEC require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations have and will likely continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404") requires an annual management assessment of the effectiveness of our internal control over financial reporting. While Section 404 also requires, among other things, that we assess the effectiveness of our internal control structure and procedures for financial reporting on an annual basis, for as long as we are a non-accelerated filer or a smaller reporting company, the registered public accounting firm that issues an audit report on our financial statements will not be required to attest to or report on the effectiveness of our internal control over financial reporting pursuant to Section 404. Our compliance with Section 404 requires that we incur substantial expense and expend significant management efforts.

During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend in part on CROs to provide timely and accurate notice of their costs to us.

Provisions in our amended and restated certificate of incorporation and amended and restated 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 amended and restated certificate of incorporation and amended and restated 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, among other things:

- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- provide that our directors may be removed only for cause;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- provide for a staggered board, which will result in only a few directors being up for re-election in each calendar year;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend the bylaws;
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of our common stock to amend many of the provisions described above; and
- limit the liability of, and provide indemnification to, our directors and officers.

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 certificate of incorporation, 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.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. Nothing in our amended and restated certificate of incorporation and amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could seriously harm our business. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. In addition, the terms of our Loan Agreement with Hercules may preclude us from paying dividends without the lender's consent or at all. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

Unfavorable conditions in the global economy caused by global political unrest or conflicts, including the ongoing conflict between Russia and Ukraine and in the Middle East, may exacerbate certain risks we face.

Political unrest, international conflict, terrorism or war, such as Russia's invasion of Ukraine and the armed conflict in the Middle East, and the global response to these conflicts, including the imposition of sanctions by the United States and other countries, could create or exacerbate risks facing our business. We have evaluated our operations and partner contracts, and we currently do not expect existing conflicts to directly have a significant effect on our financial condition or results of operations. However, if hostilities persist, escalate or expand, risks that we have identified in this Quarterly Report on Form 10-Q may be materially increased. For example, if our supply arrangements or clinical operations are disrupted due to expanded sanctions or involvement of countries where we have operations or relationships, our business could be materially disrupted. Further, the use of cyberattacks could expand as part of the ongoing conflicts, which could adversely affect our ability to maintain or enhance our cyber security measures. These and other risks are described more fully in this "Risk Factors" section.

General Risk Factors

Any legal proceedings or claims against us could be costly and time-consuming to defend and could harm our reputation regardless of the outcome.

We may in the future become subject to legal proceedings and claims that arise in the ordinary course of business, such as disputes or employment claims made by our current or former employees. Any litigation, whether meritorious or not, could harm our reputation, increase our costs and may divert management's attention, time and resources, which may in turn seriously harm our business. Insurance might not cover such claims, might not provide sufficient payments to cover all the costs to resolve one or more such claims, and might not continue to be available on terms acceptable to us. A claim brought against us that is uninsured or underinsured could result in unanticipated costs and could seriously harm our business.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk when and if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased or interrupted demand for our products;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. 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.

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

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, research or commercial partners or other collaborators, including the foundations we work with, and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA, EMA and other comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA, EMA and other comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, 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 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. 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 seriously harm our business, including the imposition of significant fines or other sanctions.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could seriously harm our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. 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. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. 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 carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could seriously harm our business.

Our business could be negatively impacted by corporate citizenship and ESG matters and/or our reporting of such matters.

Institutional, individual, and other investors, proxy advisory services, regulatory authorities, consumers and other stakeholders have increasingly focused on environmental, social and governance ("ESG") practices of companies. As we look to respond to evolving standards for identifying, measuring, and reporting ESG metrics, our efforts may result in a significant increase in costs and may nevertheless not meet investor or other stakeholder expectations and evolving standards or regulatory requirements, which may negatively impact our financial results, our reputation, our ability to attract or retain employees, our attractiveness as an investment or business partner, or expose us to government enforcement actions, private litigation, and actions by stockholders or stakeholders.

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

Recent Sales of Unregistered Securities

In September 2026, we issued an aggregate of 930,712 shares of common stock upon the exercise by Biotechnology Value Fund, L.P. and certain of its affiliates of pre-funded warrants to purchase an aggregate of 930,720 shares of common stock in a cashless exchange. Each pre-funded warrant had an exercise price of $0.0001 per share. The issuance of the shares of common stock was exempt from registration under the Securities Act pursuant to Section 3(a)(9) thereof as an exchange with an existing security holder where no commission or other remuneration was paid or given for soliciting such exchange.

Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Insider Trading Arrangements

During the fiscal quarter ended September 30, 2026, the following director, adopted a “Rule 10b5-1 trading arrangement,” as defined in Regulation S-K Item 408, as follows:

On September 3, 2026, Jacob Chacko, M.D., MBA, a member of our Board of Directors, adopted a Rule 10b5-1 trading arrangement providing for the potential sale from time to time of up to 32,500 shares of our common stock. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement is until September 3, 2027.

None of our other directors or officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any “non-Rule 10b5-1 trading arrangement,” as defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation, as currently in effect.	8-K	12/15/20	3.1	
3.2	Amended and Restated Bylaws, as currently in effect.	8-K	10/02/25	3.1	
4.1	Description of Securities of the Registrant.	10-K	3/18/2026	4.1	
4.2	Form of Common Stock Certificate.	S-1/A	12/7/20	4.2	
4.3	Form of Pre-Funded Warrant issued in conjunction with February 2024 Offering.	8-K	2/9/24	4.1	
4.4	Form of Pre-Funded Warrant issued in conjunction with November 2024 Exchange.	10-Q	11/13/24	4.4	
4.5	Form of Pre-Funded Warrant issued in conjunction with December 2024 Exchange.	8-K	12/11/24	4.1	
4.6	Form of Pre-Funded Warrant issued in conjunction with November 2025 Offering.	8-K	11/7/25	4.1	
4.7	Form of Pre-Funded Warrant issued in conjunction with January 2026 Exchange.	8-K	1/26/26	4.1	
31.1	Certification of the 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.				X
31.2	Certification of the 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.				X
32.1*	Certifications of the 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.				X
101.INS	Inline XBRL Instance Document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Document.				X
104	The cover page from the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2026 has been formatted in Inline XBRL.				X

* The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of 4D Molecular Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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.

4D Molecular Therapeutics, Inc.

Date: November 12, 2026

By: /s/ David Kirn

David Kirn, M.D.
President, Chief Executive Officer and Director
Principal Executive Officer

Date: November 12, 2026

By: /s/ Kristian Humer

Kristian Humer
Chief Financial Officer
Principal Financial and Accounting Officer

Exhibit 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**

I, David Kirn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of 4D Molecular 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.

Dated: November 12, 2026

By: /s/ David Kirn
David Kirn
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 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

I, Kristian Humer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of 4D Molecular 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.

Dated: November 12, 2026

By: /s/ Kristian Humer
Kristian Humer
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 (the "Report") of 4D Molecular Therapeutics, Inc. (the "Company") for the period ended September 30, 2026, David Kirn, as President and Chief Executive Officer of the Company, and Kristian Humer, as Chief Financial Officer of the Company, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

a) the Company's Report for the period ended September 30, 2026 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Dated: November 12, 2026

By: /s/ David Kirn
David Kirn
President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 12, 2026

By: /s/ Kristian Humer
Kristian Humer
Chief Financial Officer
(Principal Financial and Accounting Officer)