UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 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: 001-43354

Kardigan, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**93-2994203**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
506 Carnegie Center Drive, Suite 201	
Princeton, NJ	**08540**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 573-3220

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 $0.00001 per share	KARD	Nasdaq Global Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 August 7, 2026, the registrant had 93,503,699 shares of common stock, $0.00001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Quarterly Report"), of Kardigan, Inc. (the "Company") contains or incorporates statements that constitute forward-looking statements within the meaning of the federal securities laws. Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this Quarterly Report on Form 10-Q may include, for example, statements about:

- the initiation, timing, progress and results of our research and development programs, preclinical studies and clinical trials;
- the anticipated timing of release of topline data from the ongoing Phase 2b Cohort 1 trial of Danicamtiv KINSHIP-DCM, the ongoing Phase 2b clinical trial of KATALYST-AV, and the ongoing KARDINAL-ASH Phase 2 clinical trial;
- the ability of clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results, and the ability of our preclinical studies to predict later clinical trial results;
- the timing, scope and likelihood of regulatory filings and approvals of our product candidates;
- our ability to deploy and develop our Prolaio platform;
- the implementation of our business model, and strategic plans for our business, programs, and current and future product candidates;
- our ability to obtain additional financing and the sufficiency of our existing cash, cash equivalents and investments to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our potential and ability to successfully manufacture and supply our current and future product candidates for clinical trials and for commercial use, if approved;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- existing regulations and regulatory developments in the U.S. and other jurisdictions;
- expectations regarding future events under collaboration and licensing agreements, including potential future payments, as well as our plans and strategies for entering into further collaboration and licensing agreements;
- general economic, industry and market conditions, including fluctuating interest rates and rising inflation;
- our ability to attract and retain the continued service of our key personnel and to identify, hire and retain additional qualified personnel;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act;
- our expectations regarding expenses and financial results, including our expected cash runway and financial performance; and
- our anticipated use of our existing cash, cash equivalents and investments, including the proceeds from our initial public offering.

These forward-looking statements are based on information available to us at the time of this Quarterly Report and current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties, and other factors. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Factors that could cause actual results to differ include, but are not limited to, those discussed in the section titled "Risk Factors" included within this Quarterly Report on Form 10-Q.

SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties, which include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future success and viability.
- We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.
- We will require substantial additional capital in order to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Our business is highly dependent on the success of our product candidates, particularly Danicamtiv for genetic DCM, Ataciguat for moderate CAVS, and Tonlamarsen for post-hospitalization management of ASH.
- If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.
- The successful development of pharmaceutical products involves a lengthy and expensive process and is highly uncertain.
- We may experience challenges with the acquisition, development, enhancement or deployment of technology necessary for our Prolaio platform.
- The regulatory approval processes of the FDA, the European Medicines Agency ("EMA"), and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- We are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical studies and clinical trials that were previously conducted for our product candidates.
- Our use of the Prolaio platform to enhance clinical trial design and execution is a novel approach that may not result in anticipated efficiencies or regulatory acceptance, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development.
- If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.
- We have concentrated our research and development efforts on the treatment of cardiovascular diseases, a field that faces certain challenges in drug development.
- The number of patients with certain cardiovascular diseases for which we are developing our product candidates has not been established with precision. If the actual number of patients with the diseases we elect to pursue with our product candidates is smaller than we anticipate, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. Even if such product candidates are successfully developed and approved, the markets for our product candidates may be smaller than we expect, and our revenue potential and ability to achieve profitability may be materially adversely affected.
- We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.
- If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, or if any of our material license agreements are terminated, we could lose our rights to key intellectual property and components enabling our technologies.
- Our success depends upon our ability to obtain and protect our intellectual property and proprietary information. If we or our licensors are unable to obtain, maintain, defend and enforce patent or other intellectual property protection for any of our current or future product candidates or platform technologies, or if the scope of the patent or other

intellectual property protection obtained is not sufficiently broad or if our intellectual property protection is not sufficiently broad or enforceable, third parties could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any of our current or future product candidates and platform technologies may be adversely affected.

- An active trading market for our common stock may not be sustained.
- The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for investors.

The summary risk factors described above should be read together with the full risk factors in the section titled "Risk Factors" and the other information set forth in this Quarterly Report, including our consolidated financial statements and related notes, as well as in other documents that we file with the Securities and Exchange Commission ("SEC"). The risks summarized above or described elsewhere in this Quarterly Report are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial, may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements.

Kardigan, Inc.
Condensed consolidated balance sheets
(in thousands, except share and per share amounts)
(unaudited)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 384,005	$ 108,989
Short-term investments	213,590	226,496
Prepaid expenses and other current assets	12,568	9,868
Total current assets	610,163	345,353
Long-term investments	63,097	—
Restricted cash	540	540
Property and equipment, net	7,568	6,493
Operating lease right-of-use assets, net	11,224	11,741
Intangible assets, net	26,418	23,225
Other non-current assets	2,776	3,590
Total assets	$ 721,786	$ 390,942
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 14,018	$ 7,990
Accrued expenses and other current liabilities	26,167	23,903
Operating lease liabilities, current	3,752	3,143
Contingent milestone liabilities, current	26,066	2,500
Total current liabilities	70,003	37,536
Operating lease liabilities, net of current portion	9,595	10,689
Contingent milestone liabilities, net of current portion	25,305	5,243
Other non-current liabilities	1,361	1,659
Total liabilities	106,264	55,127
Commitments and contingencies (Note 8)		
Redeemable convertible preferred stock, par value of $0.00001 per share; zero shares and 29,519,423 shares authorized as of June 30, 2026 and December 31, 2025, respectively; zero shares and 29,519,423 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively; aggregate liquidation preference of zero and $597,168 as of June 30, 2026 and December 31, 2025, respectively	—	586,150
Stockholders' equity (deficit):		
Preferred stock, par value of $0.00001 per share; 10,000,000 shares and zero shares authorized as of June 30, 2026 and December 31, 2025, respectively; zero shares and zero shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	—	—
Common stock, par value of $0.00001 per share; 700,000,000 shares and 53,365,000 shares authorized as of June 30, 2026, and December 31, 2025, respectively; 93,467,940 shares and 16,351,102 shares issued and outstanding as of June 30, 2026, and December 31, 2025, respectively	1	—
Additional paid-in capital	1,069,152	30,691
Accumulated other comprehensive income (loss)	(235)	63
Accumulated deficit	(453,396)	(281,089)
Total stockholders' equity (deficit)	615,522	(250,335)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 721,786	$ 390,942

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

Kardigan, Inc.
Condensed consolidated statements of operations and comprehensive loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 56,365	$ 35,839	$ 101,432	$ 54,613
General and administrative	18,867	21,286	32,510	28,590
Change in fair value of contingent milestone liabilities	43,529	—	43,529	—
Total operating expenses	118,761	57,125	177,471	83,203
Loss from operations	(118,761)	(57,125)	(177,471)	(83,203)
Other income (expense):				
Interest income	2,765	1,068	5,558	1,900
Change in fair value of preferred stock tranche obligations	—	(1,341)	—	(3,912)
Bargain purchase gain	—	—	—	5,232
Other income (expense), net	(240)	(47)	(394)	352
Loss before income taxes	(116,236)	(57,445)	(172,307)	(79,631)
Income tax benefit	—	—	—	4,167
Net loss	$ (116,236)	$ (57,445)	$ (172,307)	$ (75,464)
Net loss per share attributable to common stockholders, basic and diluted	$ (4.61)	$ (4.64)	$ (8.66)	$ (6.27)
Weighted average common shares outstanding used in calculating net loss per share attributable to common stockholders, basic and diluted	25,196,212	12,380,388	19,896,149	12,043,978
Other comprehensive loss				
Unrealized loss on investments	(145)	—	(298)	—
Total comprehensive loss	$ (116,381)	$ (57,445)	$ (172,605)	$ (75,464)

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

Kardigan, Inc.
Condensed consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit)
(in thousands, except share and per share amounts)
(unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2025	29,519,423	$ 586,150	16,351,102	$ —	$ 30,691	$ 63	$ (281,089)	$ (250,335)
Issuance of Series B Preferred Stock	468,053	11,397	—	—	—	—	—	—
Issuance of common stock as consideration for acquired in-process research and development	—	—	44,729	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	179,266	—	427	—	—	427
Vesting of early-exercised stock options	—	—	—	—	148	—	—	148
Stock-based compensation expense	—	—	—	—	5,358	—	—	5,358
Unrealized loss on investments, net of tax	—	—	—	—	—	(153)	—	(153)
Net loss	—	—	—	—	—	—	(56,071)	(56,071)
Balance as of March 31, 2026	29,987,476	$ 597,547	16,575,097	$ —	$ 36,624	$ (90)	$ (337,160)	$ (300,626)
Conversion of redeemable convertible preferred stock to common stock upon IPO	(29,987,476)	(597,547)	47,764,024	1	597,546	—	—	597,547
Issuance of common stock from initial public offering, net of issuance costs of $5.4 million	—	—	28,750,000	—	422,422	—	—	422,422
Issuance of common stock upon exercise of stock options	—	—	363,215	—	806	—	—	806
Vesting of early-exercised stock options	—	—	—	—	149	—	—	149
Issuance of common stock upon vesting of restricted stock units, net	—	—	15,604	—	—	—	—	—
Shares repurchased for tax withholdings on vesting of restricted stock units	—	—	—	—	(90)	—	—	(90)
Stock-based compensation expense	—	—	—	—	11,695	—	—	11,695
Unrealized loss on investments, net of tax	—	—	—	—	—	(145)	—	(145)
Net loss	—	—	—	—	—	—	(116,236)	(116,236)
Balance as of June 30, 2026	—	$ —	93,467,940	$ 1	$ 1,069,152	$ (235)	$ (453,396)	$ 615,522

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2024	6,959,334	$ 120,022	16,103,207	$ —	$ 5,954	$ —	$ (89,148)	$ (83,194)
Issuance of Series A Preferred Stock upon settlement of tranche obligations	5,148,587	98,339	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,938	—	—	2,938
Net loss	—	—	—	—	—	—	(18,019)	(18,019)
Balance as of March 31, 2025	12,107,921	$ 218,361	16,103,207	$ —	$ 8,892	$ —	$ (107,167)	$ (98,275)
Issuance of common stock upon exercise of stock options	—	—	66,305	—	120	—	—	120
Stock-based compensation expense	—	—	—	—	4,291	—	—	4,291
Net loss	—	—	—	—	—	—	(57,445)	(57,445)
Balance as of June 30, 2025	12,107,921	$ 218,361	16,169,512	$ —	$ 13,303	$ —	$ (164,612)	$ (151,309)

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

Kardigan, Inc.
Condensed consolidated statements of cash flows
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2026	**2025**
Cash flows from operating activities		
Net loss	$ (172,307)	$ (75,464)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	17,053	7,229
Integration bonus expense	—	14,360
Depreciation and amortization expense	3,221	1,527
Amortization of premiums and accretion of discounts on investments	(1,848)	—
Change in fair value of preferred stock tranche obligations	—	3,912
Change in fair value of contingent milestone liabilities	43,529	—
Acquired intellectual property rights	1,400	—
Bargain purchase gain	—	(5,232)
Deferred income tax benefit	—	(4,167)
Amortization of right-of-use assets	1,078	709
Other non-cash charges	(2,570)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,348)	(3,710)
Other non-current assets	814	(797)
Accounts payable	3,776	796
Accrued expenses and other current liabilities	920	7,620
Operating lease liabilities	(1,045)	442
Net cash used in operating activities	(107,327)	(52,775)
Cash flows from investing activities		
Proceeds from maturities of investments	185,226	—
Purchases of investments	(235,218)	—
Purchases of property and equipment	(2,090)	(2,561)
Purchases of intangible assets	—	(41)
Capitalized software development costs	(2,810)	—
Acquisition of Prolaio, net of cash acquired	—	(3,961)
Net cash used in investing activities	(54,892)	(6,563)
Cash flows from financing activities		
Proceeds from issuance of preferred stock, net of issuance cost	9,997	100,000
Proceeds from issuance of common stock upon IPO, net of underwriting discounts and commissions	427,800	—
Payments of offering costs	(1,795)	—
Proceeds from exercise of stock options	1,233	184
Net cash provided by financing activities	437,235	100,184
Net increase in cash, cash equivalents and restricted cash	275,016	40,846
Cash, cash equivalents and restricted cash at beginning of period	109,529	49,815
Cash, cash equivalents and restricted cash at end of period	$ 384,545	$ 90,661
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	384,005	90,121
Restricted cash	540	540
Total cash, cash equivalents and restricted cash	$ 384,545	$ 90,661
Supplemental disclosure of non-cash financing and investing activities		
Right-of-use asset obtained in exchange for lease obligation	$ 560	$ 278
Purchases of property and equipment included in accounts payable and accrued expenses	272	704
Conversion of redeemable convertible preferred stock to common stock upon IPO	597,547	
IPO offering costs included in accounts payable and accrued expenses	3,583	—
Issuance of preferred stock as consideration for intellectual property rights	1,400	—
Settlement of preferred stock tranche obligations	—	(1,662)
Vesting of early-exercised stock options and restricted common stock	268	120

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

Kardigan, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Organization and principal activities

Description of business

Kardigan, Inc. (the "Company") is a clinical-stage precision therapeutics company developing medicines that target the root cause of specific cardiovascular diseases where no approved treatments exist. The Company's mission is to develop multiple targeted cardiovascular treatments in parallel that bring people with cardiovascular diseases closer to the cures they deserve. The Company was incorporated in Delaware in August 2023 under the name EnCarda, Inc., and changed its name to Kardigan, Inc. in December 2024. The Company is headquartered in Princeton, New Jersey.

Stock split

On June 9, 2026 the Company effected a 1.5928-for-1 forward stock split of its issued and outstanding shares of common stock, which also resulted in a proportional adjustment to the existing conversion ratios for each series of its redeemable convertible preferred stock, and to the exercise prices and number of outstanding stock options and warrants. Accordingly, all shares of common stock, stock options, warrants, and per share information presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the stock split for all periods presented. The per share par value and authorized numbers of shares of the common stock and redeemable convertible preferred stock were not adjusted as a result of the stock split.

Initial Public Offering

On June 22, 2026, the Company completed its initial public offering ("IPO") and issued 28,750,000 shares of common stock, including 3,750,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price of $16.00 per share. In connection with the IPO, the Company received net proceeds of $422.4 million, after deducting $32.2 million in underwriting discounts and commissions, and $5.4 million in other offering costs. Immediately prior to the closing of the IPO, all shares of the Company's outstanding redeemable convertible preferred stock automatically converted into 47,764,024 shares of common stock.

In connection with the closing of the IPO, the Company's certificate of incorporation was amended and restated to authorize 500,000,000 shares of voting common stock, par value $0.00001 per share, 200,000,000 shares of non-voting common stock, par value $0.00001 per share and 10,000,000 shares of preferred stock, par value of $0.00001 per share.

Liquidity and capital resources

The Company has a limited operating history and has incurred significant net losses and negative cash flows from operations since inception. As of June 30, 2026, the Company had an accumulated deficit of $453.4 million and expects to continue incurring substantial losses for the foreseeable future as it advances its research and development programs.

Historically, the Company has financed its operations principally through the issuance and sale of redeemable convertible preferred stock and, most recently, through the proceeds from the IPO. The Company may seek to raise additional capital in the future through equity or debt financings, license agreements, or other sources of financing, although there can be no assurance that such financing will be available on terms acceptable to the Company, or at all. Even if the Company is able to acquire additional financing, the financial terms may not be satisfactory or sufficient to support its operations. Failure to generate sufficient cash flows from operations, upon approval and commercialization of one of its product candidates, if ever, raise additional capital, and reduce discretionary spending, should additional capital not become available, could have a material adverse effect on the Company's ability to achieve its intended business objectives.

As discussed in the Company's audited financial statements for the year ended December 31, 2025, included in the Company's final prospectus dated June 17, 2026, filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act of 1933, as amended, the Company previously concluded that recurring losses, negative cash flows from operations, and limited liquidity raised substantial doubt about its ability to continue as a going concern. In June 2026, the Company completed its IPO and received net proceeds of approximately $422.4 million. Upon closing of the IPO and receipt of the associated net proceeds, the Company alleviated the substantial doubt that previously existed. As of June 30, 2026, the Company's cash, cash equivalents and investments totaled $660.7 million, which the Company expects will be sufficient to fund the Company's operations for at least twelve months from the issuance date of these unaudited condensed consolidated financial statements.

2. Summary of significant accounting policies

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance refers to the authoritative pronouncements contained in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB").

The condensed consolidated financial statements include the accounts of Kardigan, Inc. and its wholly owned subsidiaries, Rancho Santa Fe Bio, Inc. ("RSF") and Prolaio, Inc. ("Prolaio"), which were acquired in June 2024 and February 2025, respectively. Refer to Note 5, "*Acquisitions and Licensing Agreements*". All intercompany balances and transactions have been eliminated upon consolidation.

Unaudited Interim Financial Information

These interim condensed consolidated financial statements have been prepared on the same basis as the Company's audited consolidated financial statements and, in the opinion of management, include all adjustments, consisting solely of normal recurring adjustments, considered necessary for a fair statement of the Company's financial position as of June 30, 2026, and its results of operations and cash flows for the three and six months ended June 30, 2026 and 2025. The results of operations for the three and six months ended June 30, 2026 are not necessarily indicative of results to be expected for the full year ending December 31, 2026 or any other subsequent period. The condensed consolidated balance sheet as of December 31, 2025 was derived from the audited consolidated financial statements but does not include all disclosures required by U.S. GAAP. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto as of and for the year ended December 31, 2025, included in our final prospectus dated June 17, 2026 filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

Use of estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. The Company bases its estimates on historical experience and various other assumptions believed to be reasonable under the circumstances. Significant estimates and assumptions include, but are not limited to: the fair value of common stock prior to the Company's initial public offering, the fair value of common stock warrants, the fair value of preferred stock tranche obligations, purchase price allocations for acquisitions, the fair value of contingent milestone liabilities, the valuation of stock-based awards, the assessment of useful life and recoverability of long-lived assets, the estimated incremental borrowing rate used in operating lease calculations, the accrual of research and development costs, and the valuation allowance for deferred tax assets. Actual results could differ from those estimates and assumptions, and such differences could be material to the Company's financial position and results of operations.

Operating segments

The Company operates and manages its business as a single operating and reportable segment, focused on the discovery and development of novel therapeutic products to treat cardiovascular disease. The Company's Chief Executive Officer, who serves as the Chief Operating Decision Maker ("CODM"), reviews condensed consolidated financial information based on net income, for purposes of making operating decisions, allocating resources and assessing financial performance.

Risks and uncertainties

Global economic and business activities continue to face widespread macroeconomic uncertainties, including the potential for health epidemics, labor shortages, bank failures, inflation and monetary supply shifts, tariffs, changes in interest rates, recession risks and potential disruptions from the geopolitical conflicts. The Company continues to actively monitor the impact of these macroeconomic factors on its financial condition, liquidity, operations, and workforce. The extent of the impact of these factors on the Company's operational and financial performance, including its ability to execute its business strategies and initiatives in the expected timeframe, will depend on future developments, which are uncertain and cannot be

predicted; however, any continued or renewed disruption resulting from these factors could negatively impact the Company's business.

The Company's future results of operations involve a number of risks and uncertainties common to clinical stage companies in the biotechnology industry. The Company's product candidates are in development and the Company operates in an environment of rapid technological change and substantial competition from other pharmaceutical and biotechnology companies. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's potential drug candidates, uncertainty of market acceptance of any of the Company's product candidates that receive regulatory approval, competition from new technological innovations, substitute products and market competition, securing and protecting proprietary technology, the ability to obtain and maintain intellectual property protection, strategic relationships and dependence on key individuals and vendors.

Products developed by the Company require approvals from the U.S. Food and Drug Administration (the "FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance that any of the Company's product candidates will receive the necessary approvals. If the Company is denied approval, approval is delayed or the Company is unable to maintain approvals, it could have a materially adverse impact on the Company. 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 expects to incur substantial operating losses for the foreseeable future and will require additional financing to complete its clinical trials, perform other research and development activities, and further develop its Prolaio technology platform, and, if regulatory approval is obtained, to launch and commercialize its product candidates. There can be no assurance that such financing will be available when needed or will be on terms acceptable to the Company.

Concentration of credit risk and of significant suppliers

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and investments. The Company maintains its cash, cash equivalents and investments, which at times exceed insurance limits, at major financial institutions. The Company is exposed to credit risk in the event of default by the financial institution holding its cash to the extent recorded in the condensed consolidated balance sheets. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company's investment policy limits investments to high credit quality securities issued by the U.S. government, U.S. government-sponsored agencies, highly rated banks, and corporate issuers, subject to certain concentration limits and restrictions on maturities.

The Company is dependent on third-party contract manufacturing organizations ("CMOs") to supply drug substance and drug product for all of the Company's product candidates, for use in the preclinical studies, clinical trials and related testing. The Company currently relies, and expects to continue to rely, on a limited number of qualified manufacturers for these activities. The progress and completion of the ongoing and planned preclinical studies and clinical trials could be adversely affected by a significant interruption in the supply.

Cash, cash equivalents and restricted cash

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. Cash equivalents primarily consist of investments in money market accounts.

Restricted cash represents amounts that are legally restricted as to withdrawal or use under the terms of certain contractual agreements. The Company's restricted cash consists of cash deposited with a financial institution as collateral for a letter of credit required under the Company's lease agreements. Restricted cash is presented separately on the condensed consolidated balance sheets.

Investments

The Company's investments consist of marketable debt securities. Marketable debt securities with contractual maturities of less than 12 months at the balance sheet date are considered short-term marketable securities. Marketable debt securities with contractual maturities of 12 months or greater at the balance sheet date are considered long-term marketable

securities. The Company classifies all investments held as available-for-sale. Available-for-sale securities are recorded at fair value based upon market prices at period end, with the unrealized gains and losses reported in other comprehensive loss.

The amortized cost of debt securities classified as available-for-sale is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income in the condensed consolidated statements of operations and comprehensive loss. Realized gains and losses and declines in value due to credit-related factors on available-for-sale securities are included in other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. The cost of securities sold is based on the specific identification method. Interest on securities classified as available-for-sale is included in interest income in the condensed consolidated statements of operations and comprehensive loss.

At each balance sheet date, the Company assesses available-for-sale debt securities in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in other income (expense), net. The Company evaluates whether it intends to sell, or whether it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. The Company also evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other income (expense), net. No impairment charges or credit losses were recognized during any of the periods presented.

Internal use software

The Company capitalizes costs related to the development of internal use of enterprise-level business software in support of its clinical trials and other operational needs. Costs incurred in the application development phase are capitalized, and presented within intangible assets, net on the condensed consolidated balance sheets. These costs are amortized on a straight-line basis over the estimated useful lives, which are generally three to seven years, beginning when the software is available for its intended use. Costs related to planning and preliminary project activities, as well as post-implementation activities are expensed as incurred, and recorded within research and development ("R&D") expenses in the condensed consolidated statements of operations and comprehensive loss.

Deferred offering costs

The Company capitalizes certain legal, accounting and other third-party fees that are incremental and directly attributable to in-process equity financings until such financings are consummated. Upon consummation of an equity financing, deferred offering costs are offset against the related financing proceeds within additional paid-in capital. Should the planned financing be abandoned, the deferred offering costs are expensed immediately as a charge to general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss.

No deferred offering costs were capitalized as of December 31, 2025. In connection with the Company's IPO, which closed on June 22, 2026, the Company incurred $5.4 million of offering costs, which were recorded as a reduction to additional paid-in capital within stockholders' equity (deficit) in the accompanying condensed consolidated balance sheets as of June 30, 2026.

Fair value measurement

The Company accounts for recurring and non-recurring fair value measurements in accordance with ASC 820, which defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value, and requires expanded disclosures about fair value measurements.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The ASC 820 hierarchy ranks the quality of reliability of inputs, or assumptions, used in the determination of fair value and requires assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

- Level 1—Quoted prices in active markets for identical assets or liabilities

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

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The carrying amounts of cash equivalents, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair values because of their short-term nature.

Property and equipment, net

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is recorded using the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the shorter of their estimated useful lives or the remaining lease term of the related asset. Expenditures that extend an asset's useful life or improve its functionality are capitalized, while routine repairs and maintenance are expensed as incurred.

Upon disposal or retirement of assets, the cost and related accumulated depreciation are removed from the condensed consolidated balance sheets, and the resulting gain or loss is recognized in the condensed consolidated statements of operations and comprehensive loss in the period realized. Property and equipment held for sale are carried at fair value less costs to sell.

The estimated useful lives of the Company's property and equipment are as follows:

Asset Classification	Estimated Useful Life
Laboratory equipment	5 years
Furniture and fixtures	5 years
Office equipment	3 years
Computer equipment	3 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Business acquisitions, including goodwill, intangible assets and contingent consideration

The Company evaluates mergers, acquisitions of assets, and other similar transactions to assess whether the transaction should be accounted for as a business combination or asset acquisition, by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen is not met, the Company further evaluates whether it has acquired inputs and processes that have the ability to create outputs which would meet the definition of a business.

The Company accounts for transactions that meet the definition of a business as business combinations using the acquisition method of accounting. Under this method, the identifiable assets acquired, including identifiable intangible assets, and liabilities assumed are recognized at their estimated fair values as of the acquisition date. Any excess of the consideration transferred over the estimated fair value of the net identifiable assets acquired is recorded as goodwill. Excess of the fair value of the net assets acquired over the purchase price is recorded as a bargain purchase gain.

Intangible assets acquired in a business combination related to in-process research and development ("IPR&D") are classified as indefinite-lived until the underlying research and development activities are completed or abandoned.

In circumstances where the Company is required to pay future consideration that is contingent upon the achievement of specified milestone events, the Company recognizes a liability equal to the estimated fair value of the contingent payments as of the acquisition date. The liability is remeasured at each reporting period, with fair value changes recorded in R&D expenses in the condensed consolidated statements of operations and comprehensive loss.

Transaction costs associated with business combinations are expensed as they are incurred, and are recorded within general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss.

Asset acquisitions and acquired in-process research and development

The Company accounts for acquisitions of assets or a group of assets as asset acquisitions when substantially all of the fair value of the gross assets acquired are concentrated in a single asset or group of similar assets or when the definition of a business is not met. In an asset acquisition, the cost to acquire the asset or group of assets, including certain transaction costs, is allocated to the identifiable assets acquired and liabilities assumed based on their relative fair values as of the acquisition date. No goodwill is recognized in asset acquisitions.

Assets acquired for use in research and development activities that have an alternative future use are capitalized as IPR&D assets. Acquired IPR&D with no alternative future use is recognized as R&D expense on the acquisition date.

The Company recognizes future payments such as those upon the achievement of certain regulatory, development, or sales milestones in an asset acquisition when the underlying milestones are probable to be achieved. Milestone payments made to third parties subsequent to regulatory approval may be capitalized as intangible assets, if deemed to have alternative future use, and amortized over the estimated remaining useful life of the related product. Royalties will be recognized as cost of sales when the covered products are sold and royalties are payable.

Upfront payments are presented as investing outflows within the condensed consolidated statement of cash flows, when they are made in connection with the acquisition of an asset, regardless of whether the acquired asset is expensed as IPR&D or capitalized.

Intangible assets

Intangible assets consist of developed technology, other finite-lived intangible assets acquired in business combinations, as well as capitalized internal-use software development costs. Amortization is recognized using the straight-line method over the estimated useful lives of the related assets. Developed technology is amortized over a seven-year period. All other intangible assets subject to amortization are amortized over a three-year period.

Impairment of long-lived assets

The Company evaluates its long-lived assets, including property and equipment, finite-lived intangible assets and right-of-use assets, whenever events or changes in circumstances indicate that the carrying amount of assets may not be recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is required, recoverability is measured by comparing the carrying value of the asset group to the estimated future undiscounted cash flows expected to be generated over its remaining economic life. If an asset group is considered to be impaired, the impairment recognized equals the amount by which the carrying value of the asset group exceeds its fair value. If the useful life is shorter than originally estimated, the Company amortizes the remaining carrying value over the revised shorter useful life.

Leases

The Company determines whether an arrangement is or contains a lease at inception. Operating lease right-of-use (“ROU”) assets represent the Company’s right to use underlying assets during the lease term, and corresponding lease liabilities represent the obligation to make lease payments. ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term, using the discount rate implicit in the lease, if readily determinable. When the implicit rate is not readily determinable, the Company uses its incremental borrowing rate, which reflects the rate it would pay to borrow on a collateralized basis over a similar term in a comparable economic environment.

ROU assets further include initial direct costs and prepaid lease payments, and are reduced by lease incentives received. Lease terms may include options to extend or terminate when it is reasonably certain such options will be exercised.

Lease expense is recognized on a straight-line basis over the lease term. Variable lease costs are recorded as an expense in the period incurred.

The Company elected not to separate lease and non-lease components for any leases within its existing classes of assets and as a result, accounts for lease and non-lease components as a single lease component.

For short-term leases, defined as leases with a term of twelve months or less, for which there is no purchase option that the company is reasonably certain to exercise, the Company elected the practical expedient to not recognize an associated lease liability and ROU asset. Payments for short-term leases are expensed on a straight-line basis throughout the lease term and presented as operating expenses in the condensed consolidated statements of operations and comprehensive loss.

Classification and accretion of redeemable convertible preferred stock

The Company's preferred stock did not have redemption rights, except for the contingent redemption in the event of a deemed liquidation, that, in certain situations, was not solely within the control of the Company and would have called for the redemption of the then outstanding preferred stock. Therefore, prior to its conversion, the preferred stock was classified as mezzanine equity outside of stockholders' equity (deficit) on the condensed consolidated balance sheets. The Company recorded the preferred stock at fair value upon issuance, net of tranche obligations and associated issuance costs. The preferred stock was not redeemable, and a deemed liquidation event was not probable at any point prior to its conversion. As such, the carrying values of the preferred stock were not accreted to the redemption values during the periods it was outstanding. Upon the closing of the Company's initial public offering in June 2026, all outstanding shares of preferred stock automatically converted into shares of common stock.

Preferred stock tranche obligations

The purchase agreement for the Company's Series A Preferred Stock (as defined below) provided the Company with an obligation to issue and certain investors to purchase additional Series A Preferred Stock in subsequent closings upon satisfaction of certain conditions (the "preferred stock tranche obligations").

The Company determined the obligations met the definition of a freestanding instrument and recognized an associated asset or liability at fair value upon the initial issuance of the preferred stock. The preferred stock tranche obligations were subject to remeasurement at each balance sheet date, with changes in fair value recognized in the change in fair value of preferred stock tranche obligations in the condensed consolidated statement of operations and comprehensive loss. Upon settlement of each tranche, the related preferred stock tranche obligations were derecognized and the shares of preferred stock issued in connection with the settlement were recorded at fair value. Both the Second and Third Tranches of the Series A Preferred Stock subsequently closed, and no preferred stock tranche obligations remained outstanding thereafter.

Research and development expenses and related accruals

R&D expenses are recognized in the period in which the related services are rendered or goods are received. R&D expenses primarily consist of personnel-related costs, including salaries, benefits, and stock-based compensation expense; laboratory supplies and facility costs; and fees paid to third parties conducting research, preclinical, and clinical activities on behalf of the Company. Non-refundable advance payments for future R&D activities are recorded in prepaid and other assets on the balance sheet, and expensed as the related goods are delivered or services are performed.

The Company estimates accrued R&D expenses based on its evaluation of services performed but not yet invoiced, using available information such as progress reports, contractual terms, and communication with vendors. These estimates include costs related to clinical research organizations ("CROs"), investigative sites, CMOs, and professional service providers. Because contractual payment schedules may not align with the timing of services rendered, expense recognition is based on the estimated level of effort or stage of completion.

Historically, the Company's estimates of accrued R&D expenses have not differed materially from actual amounts incurred; however, changes in estimates are recognized in the period in which additional information becomes available.

Stock-based compensation expense

The Company measures compensation expense for all share-based awards based on the estimated fair value of the award on the grant date. For awards that vest solely based on continued service, stock-based compensation is recognized on a straight-line basis over the requisite service period. The Company recognizes expense related to stock options that contain performance conditions only when it is considered probable that the performance condition will be achieved. For

performance and market awards, stock-based compensation expense is recognized over the requisite service period using the accelerated attribution method. The Company accounts for forfeitures as they occur.

The fair value of service-based stock options is determined on the grant date using the Black-Scholes option pricing model, which incorporates assumptions including the fair value of the Company's common stock, expected term, expected volatility, risk-free interest rate, and expected dividend yield.

Awards containing market-based conditions are valued using a Monte Carlo simulation model at the grant date, which uses assumptions similar to the Black-Scholes model and incorporates Level 3 inputs related to the likelihood of satisfying market conditions. Compensation expense for awards with market conditions is recognized using the accelerated attribution method over the requisite service period, regardless of whether the market condition is ultimately satisfied.

The Company records proceeds from the early exercise of options as a non-current liability in the condensed consolidated balance sheets, and reclassifies this liability to additional paid-in capital as the Company's repurchase right lapses. The shares purchased by the option holders pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be outstanding until those shares have vested.

Determination of fair value of common stock

The Company's common stock is listed on the Nasdaq Global Market and its fair value is based on the closing price of the Company's common stock as reported on Nasdaq as of the applicable measurement date.

Prior to the Company's IPO, in the absence of an active market for the Company's common stock, the estimated fair value of our common stock has been determined by the board of directors as of the date of each applicable measurement date, with input from management, considering our most recently available third-party valuations of common stock, and the board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the applicable measurement date. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.

- Option Pricing Method ("OPM"). Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the redeemable convertible preferred stock and common stock are inferred by analyzing these options. This method is appropriate to use when the range of possible future outcomes is so difficult to predict that estimates would be highly speculative, and dissolution or liquidation is not imminent.
- Probability-Weighted Expected Return Method ("PWERM"). The PWERM is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.
- Hybrid Method. The Hybrid Method is a hybrid between PWERM and OPM, where the equity value is estimated based on probability-weighted value across multiple scenarios where the OPM is used to estimate the allocation of value within one or more of those scenarios.

Based on our early stage of development, the difficulty in predicting the range of specific outcomes (and their likelihood), and other relevant factors, the OPM allocation method was considered most appropriate for valuations prior to December 31, 2025. The OPM treats common stock and redeemable convertible preferred stock as call options on the equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under the OPM, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the redeemable convertible preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. Beginning with our February 12, 2026 valuation, we transitioned from an OPM approach to a hybrid valuation method, which we determined was most appropriate based on our stage of development and increased visibility into potential liquidity outcomes. Under the hybrid method, the overall equity value is probability weighted across multiple potential future outcomes, including an initial public offering and a remain private scenario.

Income taxes

The Company accounts for income taxes under an asset and liability approach for deferred income taxes, which requires recognition of deferred income tax assets and liabilities for the expected future tax consequences of events that have been recognized in the condensed consolidated financial statements but have not been reflected in taxable income. Estimates and judgments occur in the calculation of certain tax liabilities and in the determination of the recoverability of certain deferred tax assets, which arise from temporary differences and carryforwards. Deferred tax assets and liabilities are measured using the currently enacted tax rates that apply to taxable income in effect for the years in which those temporary differences are expected to be realized or settled. The Company regularly assesses the likelihood that deferred tax assets will be realized. To the extent that any amounts are believed to not be more-likely-than-not to be realized, a valuation allowance is recorded to reduce the deferred tax assets. The Company regularly assesses the need for a valuation allowance on deferred tax assets, and to the extent that an adjustment is needed, such adjustment will be recorded in the period that the determination is made. The Company recognizes tax benefits from uncertain tax positions only if it believes the position is more likely than not to be sustained upon examination by the taxing authorities based on the technical merits. The tax benefits recognized are measured as the largest amount of tax benefit that is more likely than not to be realized upon settlement. The Company recognizes interest and penalties related to income tax matters as income tax expense. To date, there have been no interest charges or penalties related to unrecognized tax benefits.

Net loss per share

Net loss per share attributable to common stockholders is calculated using the two-class method, as the Company's preferred stock represents participating securities that participate in earnings on a non-cumulative basis when dividends are declared on common stock.

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, excluding shares subject to vesting or forfeiture, without consideration for potentially dilutive securities. Diluted net loss per share attributable to common stockholders is calculated by giving effect to all potentially dilutive securities outstanding for the period utilizing the treasury stock method or the if-converted method based on the nature of such securities. Diluted net loss per share is the same as basic net loss per share in periods when the effects of potentially dilutive shares of common stock are antidilutive.

In periods of net income, distributed and undistributed earnings are allocated to participating securities based on their contractual participation rights.

Comprehensive loss

Comprehensive loss includes all changes in equity (net assets) during a period from non-owner sources, including unrealized gains and losses on investments. Comprehensive gains and losses have been reflected in the condensed consolidated statements of operations and comprehensive loss.

Emerging growth company

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (1) no longer an emerging growth company and (2) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act, unless early adoption is permitted. As a result, these condensed consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recent accounting pronouncements - Not yet adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40)*, which requires new tabular disclosures for specified categories of expenses. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the potential impact of this guidance on its condensed consolidated financial statements and disclosures.

In September 2025, the FASB issued ASU 2025-06, *Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*, which amends certain aspects of the accounting for, and disclosure of, internal-use software costs under ASC 350-40, *Intangibles — Goodwill and Other - Internal-Use Software*. ASU 2025-06 is intended to simplify and modernize the accounting for internal-use software costs by removing all references to prescriptive and sequential software development stages under Subtopic 350-40. The amendments in ASU 2025-06 are effective for annual reporting periods beginning after December 15, 2027, and interim reporting periods within those annual reporting periods, with early adoption permitted as of the beginning of an annual reporting period. The guidance can be applied prospectively, retrospectively or under a modified transition approach. The Company is currently assessing the impact of the adoption of this guidance on its condensed consolidated financial statements and disclosures.

In September 2025, the FASB issued ASU 2025-07, *Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606): Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract*, which clarifies the application of derivative accounting to certain contracts and refines the guidance for share-based noncash consideration received from customers. Specifically, ASU 2025-07 introduces a scope exception for contracts that are not exchange-traded and whose underlying is tied to operations or activities specific to one party. ASU 2025-07 is effective for fiscal years beginning after December 15, 2026 and interim periods within those fiscal years, with early adoption permitted. The guidance may be applied prospectively or under a modified retrospective transition approach, and the Company is currently assessing the impact of adoption on its condensed consolidated financial statements and disclosures.

3. Fair value measurements

The following tables summarize the types of financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy. As of June 30, 2026 and December 31, 2025, financial assets and liabilities measured at fair value on a recurring basis were as follows (in thousands):

	June 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 376,979	$ —	$ —	$ 376,979
Short-term investments:				
U.S. treasury bills	—	82,246	—	82,246
U.S. government bonds	—	33,012	—	33,012
Corporate bonds	—	98,332	—	98,332
Long-term investments:				
U.S. government agency bonds	—	9,896	—	9,896
Corporate bonds	—	53,201	—	53,201
Total assets measured at fair value	$ 376,979	$ 276,687	$ —	$ 653,666
Liabilities:				
Contingent milestone liabilities	—	—	47,346	47,346
Total liabilities measured at fair value	$ —	$ —	$ 47,346	$ 47,346

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 99,195	$ —	$ —	$ 99,195
Corporate bonds	—	5,996	—	5,996
Short-term investments:				
U.S. treasury bills	—	94,108	—	94,108
U.S. government bonds	—	43,927	—	43,927
Corporate bonds	—	88,462	—	88,462
Total assets measured at fair value	$ 99,195	$ 232,493	$ —	$ 331,688
Liabilities:				
Contingent milestone liabilities	—	—	3,817	3,817
Total liabilities measured at fair value	$ —	$ —	$ 3,817	$ 3,817

There were no transfers between Level 1, 2, or 3 during the three and six months ended June 30, 2026 and during the year ended December 31, 2025.

The following table summarizes the Company's marketable securities, that are classified as available-for-sale, as of June 30, 2026 and December 31, 2025 (in thousands):

	As of June 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Short-term investments:				
U.S. treasury bills	$ 82,280	$ —	$ (34)	$ 82,246
U.S. government bonds	33,023	—	(11)	33,012
Corporate bonds	98,421	—	(89)	98,332
Long-term investments:				
U.S. government agency bonds	$ 9,913	$ —	$ (17)	$ 9,896
Corporate bonds	53,285	—	(84)	53,201
Total investments	$ 276,922	$ —	$ (235)	$ 276,687

	As of December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Short-term investments:				
U.S. treasury bills	$ 94,045	$ 63	$ —	$ 94,108
U.S. government agency bonds	43,927	—	—	43,927
Corporate bonds	88,461	—	—	88,461
Total investments	$ 226,433	$ 63	$ —	$ 226,496

The fair values of available-for-sale securities by contractual maturity were as follows (in thousands):

	June 30, 2026	December 31, 2025
Due in 1 year or less	$ 213,590	$ 226,496
Due in 1 to 2 years	63,097	—
Total	$ 276,687	$ 226,496

As of June 30, 2026, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the issuers of the marketable securities, and the Company has no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. The Company considered the current and expected future

economic and market conditions and determined that its investments were not significantly impacted. For the three and six months ended June 30, 2026 and 2025 the Company did not recognize any impairment losses on its investments.

Series A Preferred Stock Tranche Obligations

In June 2024, the Company entered into a Series A Preferred Stock purchase agreement (Note 9, *"Redeemable Convertible Preferred Stock"*). The preferred stock tranche asset and liability represented the fair value of the Company's obligations to issue Series A Preferred Stock in two subsequent closings upon satisfaction of certain conditions. These instruments were measured at fair value on a recurring basis and were classified within Level 3 of the fair value hierarchy as the valuation incorporates significant unobservable inputs.

The fair value was determined using a probability-weighted expected return method as it represents a contingent commitment for the additional shares. The valuation reflected market-participant assumptions, and considered, among other inputs, the estimated fair value per share of the Series A Preferred Stock as of each measurement date, probability of meeting certain milestone events, the expected time until certain milestone events would be met, and the discount rate.

The most significant unobservable inputs were the estimated fair value of the Company's Series A Preferred Stock and the probability and expected timing of achieving certain milestone events as of the measurement dates. The Company determined the fair value per share of the underlying Series A Preferred Stock by taking into consideration the most recent sales of its Series A Preferred Stock, results obtained from third-party valuations and additional factors the Company deemed relevant. Changes in these inputs can materially affect the fair value of the preferred stock tranche obligations.

The following table presents the most significant assumptions used in the probability-weighted expected return model to determine the fair value of the Series A Preferred Stock tranche obligations during the periods presented:

	June 30, 2025	
	Second Tranche	Third Tranche
Probability of achieving milestone	90%	100%
Risk free rate	4.45%	N/a
Term until milestone is achieved (years)	0.3	N/a

Fair value of Series A Preferred Stock was $21.24 per share as of June 30, 2025.

The following table presents a summary of the changes in the fair value of the Series A Preferred Stock tranche obligations, asset/(liability) for the six months ended June 30, 2025 (in thousands):

	Second Tranche	Third Tranche
Balance as of December 31, 2024	$ (7,284)	$ 1,662
Change in fair value	(3,912)	—
Settlement of preferred stock tranche obligation	—	(1,662)
Balance as of June 30, 2025	$ (11,196)	$ —

During the six months ended June 30, 2025, upon the closing of the Third Tranche, the related preferred stock tranche obligation was derecognized and the shares of preferred stock issued in connection with the settlement were recorded at the fair value as of settlement date. No change in fair value was recognized in the condensed consolidated statement of operations and comprehensive loss upon settlement of the Third Tranche obligation.

During the six months ended June 30, 2025, the Company remeasured the Second Tranche obligation, and the associated change in fair value of preferred stock tranche obligation of $3.9 million was recognized in the condensed consolidated statement of operations and comprehensive loss.

Both the Second and Third Tranches of the Series A Preferred Stock were closed during the year ended December 31, 2025, and accordingly, no change in fair value was recorded for the six months ended June 30, 2026.

Prolaio Contingent Milestone Liabilities

On February 24, 2025, the Company acquired Prolaio, Inc., and, as part of the consideration transferred in the acquisition, recognized a contingent consideration liability. The liability represented the estimated fair value of future milestone payments of up to $200.0 million payable to Prolaio's former stockholders upon the achievement of specified post-closing operational, financial and regulatory milestones. On May 1, 2026, the Company entered into an amendment to the Agreement and Plan of Merger with Prolaio's former stockholders to amend the applicable milestone provisions, which replaced the original milestones with new milestones tied to the Company's achievement of specified valuation thresholds through May 2032, while keeping the aggregate maximum milestone payments unchanged at $200.0 million (Note 5, "*Acquisitions and Licensing Agreements*").

The following table presents a summary of the changes in the fair value of the Prolaio contingent milestone liabilities (in thousands):

	Amount
Balance as of December 31, 2024	$ —
Initial recognition upon acquisition	4,585
Change in fair value	—
Balance as of June 30, 2025	$ 4,585

	Amount
Balance as of December 31, 2025	$ 3,817
Change in fair value	43,529
Balance as of June 30, 2026	$ 47,346

The Company utilizes significant estimates and assumptions it believes would be made by a market participant in determining the estimated fair value of contingent milestone liabilities at each balance sheet date.

Prior to the amendment, the fair value of the Prolaio contingent consideration was determined by calculating the probability-weighted estimated value of the specified milestone payments, based on the assessment of the likelihood and estimated timing that the milestones would be achieved and the applicable discount rates. The discount rate captured the credit risk associated with the payment of the contingent consideration when earned and due.

As of the amendment date and subsequently, the fair value of the Prolaio contingent milestone liabilities was determined based on the Monte Carlo valuation method, reflecting the shift to valuation-based milestones tied to the Company's market valuation thresholds through May 2032.

The fair value of the Prolaio contingent milestone liabilities as of the respective dates were calculated using the following unobservable inputs:

	December 31, 2025		June 30, 2025	
	Range	Weighted Average	Range	Weighted Average
Discount rates	14.99%	14.99%	9.90%-10.19%	10.14%
Probability of milestone achievement	0.3%-4.9%	1.98%	0.3%-4.9%	1.98%

	June 30, 2026	May 1, 2026
Expiration date	5/1/2032	5/1/2032
Starting stock price	$ 23.85	$ 21.37
Risk-free rate	4.15%	4.30%
Cost of debt rate	19.00%	14.40%
Volatility	95%	95%

The estimated fair value of contingent milestone liabilities may change significantly as development progresses and additional data is obtained, impacting the assumptions regarding probabilities of successful achievement of the Company's valuation thresholds used to estimate the fair value of the liability and the timing in which they are expected to be achieved. In evaluating the fair value assumptions, judgment is required to interpret the market data used to develop the estimates. Accordingly, the use of different market assumptions, inputs and/or different valuation techniques could result in materially different fair value estimates.

PhysIQ Contingent Consideration (Assumed Liability)

The Company utilized significant estimates and assumptions it believes would be made by a market participant in determining the estimated fair value of the contingent consideration liability. The fair value of the PhysIQ contingent consideration, as of the acquisition date, was determined by calculating the probability-weighted estimated value of the specified milestone payments, based on the assessment of the likelihood and estimated timing that the milestones would be achieved and the applicable discount rates. The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due.

The fair value of the PhysIQ contingent consideration as of the acquisition date was $3.3 million and was calculated using the following unobservable inputs:

	February 24, 2025	
	Range	Weighted Average
Discount rates	9.90%-10.15%	10.10%
Probability of milestone achievement	10.0%-80.0%	20.63%

The weighted-average unobservable inputs were calculated based on the relative value of the specified milestones. The estimated fair value of contingent consideration liabilities may change significantly as development progresses and additional data is obtained, impacting the assumptions regarding probabilities of successful achievement of the milestones used to estimate the fair value of the liability and the timing in which they are expected to be achieved. In evaluating the fair value assumptions, judgment is required to interpret the market data used to develop the estimates. Accordingly, the use of different market assumptions, inputs and/or different valuation techniques could result in materially different fair value estimates. Following the initial recognition at the acquisition date, the acquired contingency is not subsequently measured at fair value. Refer to Note 5, "*Acquisitions and Licensing Agreements*" for further details on the change in the carrying value of the PhyslQ contingent consideration.

4. Balance sheet components

Property and equipment, net

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

	June 30, 2026	December 31, 2025
Laboratory equipment	6,275	$ 5,251
Computer equipment	946	798
Furniture & fixtures	570	507
Leasehold improvements	649	396
Office equipment	243	184
Construction in progress	833	370
Property and equipment, gross	$ 9,516	$ 7,506
Less: accumulated depreciation	(1,948)	(1,013)
Property and equipment, net	$ 7,568	$ 6,493

Depreciation expense was $0.4 million, $0.9 million for the three and six months ended June 30, 2026, and $0.1 million and $0.2 million for the three and six months ended June 30, 2025, respectively.

Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2026	December 31, 2025
Accrued clinical trial expenses	12,995	$ 9,154
Accrued personnel and related expenses	8,197	9,128
Accrued manufacturing expenses	917	2,355
Other	4,058	3,266
Total accrued expenses and other current liabilities	$ 26,167	$ 23,903

5. Acquisitions and licensing agreements

Acquisition of Prolaio, Inc.

On February 24, 2025 (the "Acquisition Date"), the Company acquired 100% of the outstanding shares of Prolaio, Inc., a healthcare technology company focused on cardiovascular data collection and analytics. The acquisition provides the Company with access to Prolaio, Inc.'s cardiovascular data platform, to enhance and accelerate the Company's research and development portfolio of late-stage cardiovascular disease assets. At the time of the acquisition, Tassos Gianakakos, the Company's Chief Executive Officer and member of the Company's board of directors, also served as Prolaio, Inc.'s Chief Executive Officer and as a member of its board of directors and Jay Edelberg, the Company's Chief Medical Officer, served as its Head of Research & Development and as a member of its board of directors. Mr. Gianakakos and Dr. Edelberg beneficially owned 55.7% and 17.1%, respectively, of Prolaio at the time of its acquisition. Accordingly, the Prolaio acquisition itself constituted a related-party transaction. Refer to Note 15, *"Related Party Transactions"* for further details.

The Company concluded that Prolaio constituted a business under ASC 805 and the transaction was accounted for as a business combination.

The total purchase consideration transferred was approximately $8.6 million, consisting of approximately $4.0 million in cash, primarily used to repay $4.0 million of promissory notes held by Mr. Gianakakos' family's trusts, and fair value of contingent consideration of $4.6 million, representing the estimated acquisition date fair value of milestone payments of up to $200.0 million, payable in cash or shares, contingent on the achievement of various post-closing milestones (the "Prolaio Contingent Consideration"). The Prolaio Contingent Consideration was recognized as contingent milestone liabilities on the condensed consolidated balance sheet.

Acquisition related costs of approximately $0.8 million, consisting primarily of legal, accounting, and valuation fees, were expensed as incurred and recorded within general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss.

The following table summarizes the fair values of the identifiable assets acquired and liabilities assumed as of the Acquisition Date (in thousands):

	Amount
Assets acquired:	
Cash and cash equivalents	$ 14
Inventory	244
Prepaid expenses and other current assets	390
Property and software	175
Developed technology	25,400
In-process research and development (IPR&D)	1,100
Operating lease right-of-use assets, net	255
Other non-current assets	57
Total assets acquired	27,635
Liabilities assumed:	
Accounts payable	2,710
Accrued expenses and other current liabilities	2,717
Deferred revenue	270
Operating lease liability	109
Assumed contingent consideration liability	3,300
Deferred income tax liability	4,512
Other liabilities, non-current	205
Total liabilities assumed	13,823
Net assets acquired	$ 13,812

In connection with this acquisition, the Company recorded $13.8 million of net assets acquired, primarily consisting of developed technology with a fair value of $25.4 million, IPR&D with a fair value of $1.1 million, and $13.8 million in liabilities assumed, including $4.5 million of deferred income tax liability and $3.3 million of assumed contingent consideration liability. Because the fair value of net identifiable assets acquired exceeded the fair value of the consideration transferred, the Company recognized a gain on bargain purchase in the amount of $5.2 million in the condensed consolidated statement of operations and comprehensive loss for the six months ended June 30, 2025. The bargain purchase gain reflects the Company's ability to acquire Prolaio at a purchase price below the fair value of the acquired net assets due to a combination of factors, including Prolaio's limited operating scale, historical operating losses, liquidity constraints at the time of the transaction, and the structure of the consideration transferred. In particular, concurrent with the acquisition, the Company entered into integration bonus arrangements with the Company's Chief Executive Officer and Chief Medical Officer ("Integration Bonus"), both of whom were co-founders and Prolaio shareholders. These arrangements were contingent upon post-combination services and successful integration and, accordingly were accounted for as compensation expense rather than consideration transferred.

Prolaio's results of operations were included in the Company's condensed consolidated statement of operations and comprehensive loss from the date of acquisition, February 24, 2025.

Pro forma financial information

The following pro forma combined financial information has been prepared to give effect to the Prolaio acquisition as if it had been consummated on January 1, 2024, and was prepared using the historical results of Kardigan and Prolaio for the three and six months ended June 30, 2025 (in thousands):

	Three Months Ended June 30,	Six Months Ended June 30,
	2025	2025
Net loss	$ (43,085)	$ (73,604)

The pro forma amounts have been adjusted for:

- transaction costs of $1.0 million were excluded from the six months ended June 30, 2025 pro forma results, as if these costs were incurred during the 2024 period;
- gain on bargain purchase of $5.2 million was excluded from the six months ended June 30, 2025 pro forma results, as if such gain was recognized during the 2024 period;
- income tax benefit of $4.2 million was excluded from the six months ended June 30, 2025 pro forma results, as if such benefit was recognized during the 2024 period;
- incremental stock-based compensation expense related to the accelerated vesting of Prolaio options upon acquisition of $1.6 million was excluded from the six months ended June 30, 2025 pro forma results, as if this expense was incurred during the 2024 period;
- incremental intangible assets amortization expense resulting from the fair value adjustment recognized for developed technology in the amount of $0.6 million was included in six months ended June 30, 2025 pro forma results;
- incremental stock-based compensation expense related to the integration bonus of $14.4 million was excluded from the three and six months ended June 30, 2025 pro forma results;
- immaterial inter-company transactions between the Company and Prolaio during the six months ended June 30, 2025 were eliminated.

The Company had no revenue for the three and six months ended June 30, 2025.

The pro forma data is presented for informational purposes only and is not intended to represent or be indicative of the results of operations that would have been reported had the acquisition occurred on that date, nor is it intended to be representative of future results of operations of the combined company.

Acquired developed technology

Developed technology acquired consists of the cardiovascular analytics data platform originally obtained by Prolaio in November 2023 through its purchase of certain assets from PhysIQ (defined below). Subsequent to the asset purchase and prior to the Company's acquisition of Prolaio, Prolaio's engineering team enhanced the acquired technology and expanded the platform capabilities through the addition of new features and functional improvements.

As of the Acquisition Date, the fair value of the developed technology was estimated using the cost method, which incorporates management's estimates of the costs that would be incurred to develop the technology from scratch, including assumptions regarding required personnel, annual compensation, and the expected development timeline. The Company estimated that it would require approximately 3.7 years for a team of approximately 50 employees, with an estimated average annual cost ranging from $0.1 million to $0.2 million per employee, to recreate the technology, resulting in a total valuation of $25.4 million.

Prolaio contingent milestone liabilities

As part of the consideration transferred in the acquisition, the Company was required to make contingent cash payments up to $200.0 million, dependent upon the achievement of certain specified post-closing operational, financial and regulatory milestones ("Prolaio milestones") prior to February 2029. Specifically, Prolaio milestones depended on the success of the Company's clinical trials, achievement of certain Prolaio revenue targets (excluding intercompany revenue), and adoption and performance of the Prolaio platform. The fair value of the Prolaio Contingent Consideration at the acquisition date was $4.6 million. It was estimated using a probability weighted discounted cash flow model, which incorporated management's estimates of the probability and timing of milestone achievement as of the acquisition date. The milestones were contractually required to be achieved within four years from the date of acquisition, discounted at a rate of approximately 10%.

On May 1, 2026, the Company entered into an amendment to the Agreement and Plan of Merger with the former stockholders of Prolaio in order to amend the milestone provisions applicable to such stockholders, including Mr. Gianakakos and Dr. Edelberg ("Prolaio amendment"). In particular, the milestones were revised to: (i) better align the incentives of the former stockholders of Prolaio, Inc., in their capacities as executive officers and employees of Kardigan, with the creation of stockholder value for the Company; and (ii) better reflect the Company's current operations and strategic direction following

the acquisition, including the Company's focus on deploying the Prolaio platform in support of its own clinical trials, and (iii) ensure that the milestones remained aligned with the Company's business. Pursuant to the amendment and subject to the conditions therein, the former stockholders of Prolaio, Inc., including Mr. Gianakakos and Dr. Edelberg, are entitled to milestone payments based on certain Company valuations, as defined in the agreement, as follows: (i) up to $50 million upon the Company's achievement of a valuation equal to or greater than $5.0 billion; (ii) up to $50 million upon the Company's achievement of a valuation equal to or greater than $6.0 billion; and (iii) up to $100 million upon the Company's achievement of a valuation equal to or greater than $12.0 billion; in each case to the extent such milestones are achieved on or before May 1, 2032. If such milestone payments become payable in full, Mr. Gianakakos is entitled to receive payments of up to $12.9 million, $31.3 million and $62.4 million, respectively, pursuant to each milestone, for a total of up to $106.6 million; and Dr. Edelberg is entitled to receive payments of up to $3.6 million, $9.8 million, and $19.5 million, respectively, pursuant to each milestone, for a total of up to $32.9 million.

None of the Prolaio milestones, original or amended, have been achieved and no milestone payments have been made.

The Prolaio contingent payments are classified as Level 3 within the fair value hierarchy, due to the use of significant unobservable inputs and remeasured at fair value at each reporting date. Prior to the Prolaio amendment, changes in the fair value of the contingent consideration were recognized in R&D expenses in the condensed consolidated statements of operations and comprehensive loss. Subsequent to the Prolaio amendment, changes in the fair value of the contingent milestone liabilities are recognized in change in fair value of contingent milestone liabilities, in the condensed consolidated statements of operations and comprehensive loss. The fair value of the Prolaio Contingent Consideration was $3.8 million as of December 31, 2025. Upon the Prolaio amendment, on May 1, 2026, the Prolaio Contingent Consideration was settled and the new contingent milestone liabilities were recognized at an initial fair value of $13.7 million. The fair value of the contingent milestone liabilities was $47.3 million as of June 30, 2026. The Company recognized a $43.5 million increase in the fair value of contingent milestone liabilities, which is presented within change in fair value of contingent milestone liabilities in the condensed consolidated statements of operations, for both the three and six months ended June 30, 2026. No change in fair value was recorded in the three and six months ended June 30, 2025.

PhysIQ contingent consideration (assumed liability)

Liabilities assumed as part of the Company's acquisition of Prolaio included a contingent consideration liability associated with Prolaio's historical acquisition of certain assets of PhysIQ, Inc. ("PhysIQ contingent consideration"), a health technology company specializing in cloud-based predictive analytics for personalized physiology. The obligation of up to $20.0 million, payable in cash, is contingent upon the achievement of certain sales milestones ("PhysIQ milestones").

As of the acquisition date, the Company recognized this contingent consideration at fair value using a probability-weighted approach, which incorporates management's estimates of the probability and timing of milestone achievement. The milestones are expected to be achieved within 4 years from the date of acquisition of Prolaio, and are discounted at a rate of approximately 10%. The estimated fair value of the PhysIQ contingent consideration at the acquisition date was $3.3 million, which was recorded within contingent milestone liabilities on the condensed consolidated balance sheet.

Following the acquisition date, the Company applies a systematic and rational approach and recognizes additional amounts related to the PhysIQ contingent consideration when the underlying milestones are considered probable of achievement and reasonably estimable. Amounts are written off only when it is resolved that the Company will not be required to make payment or when the obligation legally expires. As such, the PhysIQ contingent consideration recorded will not be reduced below the amount recorded at the acquisition date until the obligation expires or the liability is paid.

The PhysIQ contingent consideration was $3.9 million as of June 30, 2026 and December 31, 2025. The Company recorded no expense in the condensed consolidated statement of operations and comprehensive loss for the three and six months ended June 30, 2026.

As of December 31, 2025, the milestone with a value of $2.5 million was considered probable of achievement and was expected to be achieved within 12 months of the reporting date. Accordingly, it was classified within current liabilities on the condensed consolidated balance sheet as of December 31, 2025. As of June 30, 2026, this milestone was still considered probable of achievement but was expected to be achieved within more than 12 months of the reporting date, and, accordingly, was classified within non-current liabilities on the condensed consolidated balance sheet. As of June 30, 2026, no milestone payments have been made.

Prolaio bonus integration agreements

Concurrent with the acquisition of Prolaio, the Company entered into agreements (the "Bonus Agreements") with the Company's Chief Executive Officer and Chief Medical Officer, that provided a right to a bonus in the amount of $9.0 million and $2.0 million, respectively, of shares of common stock issued in our initial public offering or convertible preferred stock, as applicable, as well as additional cash amounts intended to cover related federal, state, and local tax obligations. The Bonus Agreements also provided that, if the equity securities issued were not freely tradeable, the Company would loan each executive an amount sufficient to cover applicable tax obligations. The awards were contingent upon the closing and successful integration of Prolaio, as determined by the Company's board of directors.

The Bonus Agreements became payable upon completion of the Series B Initial Closing (as defined below). On September 4, 2025, in connection with the Series B Initial Closing, the Company entered into bonus integration agreements (the "Bonus Integration Agreements") with each executive. The Bonus Integration Agreements modified the Bonus Agreements such that (i) each recipient agreed to forfeit Series B Preferred Stock (as defined below) to satisfy the tax withholding obligations, (ii) certain payments required to be made under the Bonus Agreements would be remitted to federal and state tax authorities via payroll for certain tax liabilities required to be satisfied by us through payroll and (iii) no loan will be issued to the recipient. Pursuant to the Bonus Integration Agreements, and net of tax withholding obligations, on September 4, 2025, the Company issued an aggregate of 374,360 shares of Series B Preferred Stock, with an estimated grant date fair value of approximately $8.0 million, and subsequently remitted approximately $6.4 million in cash to satisfy the related tax obligations.

As the integration bonus payment was contingent upon post-combination services, the arrangement was accounted for as compensation. The integration bonus was deemed probable as of June 30, 2025, and the Company recognized related compensation expense of $2.6 million within research and development expenses and $11.7 million within general and administrative expenses in the three and six months ended June 30, 2025 in the condensed consolidated statement of operations and comprehensive loss. No related compensation expense was recognized in the three and six months ended June 30, 2026.

Acquisition of RSF

On June 6, 2024, the Company acquired 100% of the outstanding shares of Rancho Santa Fe Bio, Inc. ("RSF") in order to obtain certain of RSF's existing intellectual properties, including (i) a license agreement relating to Ataciguat (i.e., HMR1766) with Sanofi ("Sanofi"); and (ii) a patent license and know-how agreement with the Mayo Foundation for Medical Education and Research ("Mayo"). Total consideration was $14.8 million, and included cash of $3.5 million, the settlement of RSF's outstanding indebtedness of $10.6 million on the acquisition date and the payment of certain transaction costs of $0.7 million incurred by RSF. In addition, the former stockholders of RSF are entitled to milestone payments of up to $26.5 million in development and regulatory milestones and up to $249.5 million in sales milestones ("RSF milestones"), in each case to be allocated among such former stockholders on a pro rata basis in accordance with their respective ownership interests in RSF immediately prior to the acquisition. The Company is additionally obligated to pay to the former stockholders of RSF low single-digit royalties on worldwide net sales of any pharmaceutical product containing Ataciguat.

Under ASC 805, the Company determined that the acquisition did not meet the definition of a business at the time of the acquisition as substantially all of the fair value of the gross assets acquired were concentrated in a single identifiable asset. The Company determined that RSF was a variable interest entity ("VIE") under ASC 810 because it lacked sufficient equity to finance its activities. Upon acquisition, the Company became the primary beneficiary of RSF, and therefore was required to consolidate RSF. Accordingly, the transaction was accounted for as the acquisition of a VIE that is not a business.

The net assets acquired consisted primarily of the IPR&D asset, cash and cash equivalents in the amount of $0.2 million, and assumed accounts payable for an amount of $1.3 million. Accordingly, the consideration allocated to the IPR&D asset amounted to $15.9 million. The acquired licensed technology was determined to be an IPR&D asset that did not have alternative future use as of the acquisition date, and the full amount was recognized as R&D expense in the condensed consolidated statement of operations and comprehensive loss for the year ended December 31, 2024.

The Company achieved the first development milestone associated with Ataciguat upon dosing of the first patient in the Phase 3 clinical trial in September 2025. This milestone triggered a payment obligation of $3.0 million. In September 2025, $1.5 million was settled in cash, and the remaining $1.5 million was accrued for in the Company's condensed consolidated balance sheet as of December 31, 2025 and as of June 30, 2026 within accrued and other current liabilities.

None of the other RSF milestones have been achieved nor were deemed probable and estimable as of June 30, 2026, and no other milestone payments have been made.

Under the Sanofi and the Mayo agreements, the Company is obligated to make certain additional milestone, royalty and sublicense-related payments under these agreements, summarized further below.

License agreement with Sanofi

On June 2, 2021, RSF entered into a license agreement with Sanofi, as subsequently amended on March 18, 2022, January 9, 2023, and November 7, 2025 (collectively, the "Sanofi License"), under which RSF received a worldwide, exclusive, sublicensable (subject to certain conditions and restrictions), royalty-bearing license under certain Sanofi know-how to exploit Ataciguat and pharmaceutical products containing Ataciguat ("Ataciguat Products") for all human and mammalian therapeutic, prophylactic and diagnostic uses (the "Sanofi License Field").

If the Company succeeds in developing and commercializing Ataciguat Products, it will be obligated to pay Sanofi up to an aggregate of $14.8 million in potential commercial milestone payments ("Sanofi milestones"). The Company is also obligated to pay Sanofi tiered royalties ranging from low-single digit to mid-single digit percentages on worldwide annual net sales of Ataciguat Products by the Company or its affiliates and sublicensees.

As of June 30, 2026, none of the Sanofi milestones had been achieved nor were deemed probable and estimable, and no milestone payments have been made.

Patent license and know-how agreement with the Mayo Foundation for Medical Education and Research ("Mayo")

On December 6, 2019, RSF entered into a license agreement with Mayo, as amended on May 20, 2021, August 23, 2023, March 10, 2024, June 6, 2024 and December 22, 2025 (collectively, the "Mayo License"), under which RSF received (i) a worldwide exclusive license with the right to sublicense (through multiple tiers) under certain Mayo patent rights, (ii) a nonexclusive license with the right to sublicense (through multiple tiers in connection with a sublicense of the Mayo patent rights or know-how) to use certain know-how and materials, and (iii) a nonexclusive worldwide license, with the right to sublicense (through multiple tiers), subject to approval from Mayo, to use certain Mayo data, in each case in (i) through (iii), to develop, make, have made, use, offer for sale, sell, and import certain licensed products, including Ataciguat, for the prevention, diagnosis, and/or treatment of any and all human diseases and conditions.

The Company is obligated to pay Mayo up to $0.3 million in development and regulatory milestone payments and up to $1.3 million in commercial milestone payments ("Mayo milestones") for each licensed product. The Company is also obligated to pay Mayo royalties ranging from a mid-single digit to subteen percentage of worldwide annual net sales by the Company, its affiliates and sublicensees of licensed products. In the event that the Company is required to pay a non-affiliate third party certain consideration for a license under intellectual property rights owned or controlled by such non-affiliate third party that are required for the manufacture, use or sale of the licensed products, the Company can deduct a certain amount of such consideration from the royalty payments due to Mayo under the Mayo License, subject to a customary reduction floor. The Company's obligation to pay Mayo royalties for licensed products will expire upon the expiration date of the last to expire of the licensed patents or the last to expire regulatory exclusivity for a licensed product. Mayo is also eligible to receive a mid-double digit percentage of certain non-royalty sublicense income as well as a certain percentage of any consideration received by the Company for the sale or transfer of an FDA priority review voucher or similar transferable asset.

As of June 30, 2026, none of the Mayo milestones had been achieved nor were deemed probable and estimable, and no milestone payments have been made.

License agreement with Ionis

On June 7, 2024, the Company entered into a License Agreement (the "Ionis License Agreement") with Ionis Pharmaceuticals, Inc. ("Ionis"), pursuant to which the Company was granted an exclusive, worldwide, sublicensable (subject to certain conditions and restrictions), royalty-bearing license under certain Ionis intellectual property to develop and commercialize Tonlamarsen (formerly ION904) and products containing Tonlamarsen (the "Licensed Ionis Products") in the field of prophylactic or therapeutic use in humans (the "Ionis Licensed Field"). The Company also received a non-exclusive, worldwide, sublicensable (subject to certain conditions and restrictions), royalty-bearing license under certain Ionis intellectual property to manufacture Tonlamarsen and Licensed Ionis Products in the Ionis Licensed Field. Until the third

anniversary of the effective date of the Ionis License Agreement, or June 2027, neither party may develop or commercialize, or assist or grant a third party rights to develop or commercialize certain ASOs designed to bind to the RNA encoded by the human angiotensinogen gene, subject to certain conditions and exceptions.

As initial consideration for the Ionis License Agreement, the Company made an upfront payment of $20.0 million to Ionis. As additional consideration for the licenses and rights granted to us by Ionis, the Company is required to pay Ionis: (i) milestone payments in the event of successful achievement of specified development, regulatory and sales milestones of up to an aggregate of $375.0 million (up to $35.0 million in development and regulatory milestone payments and up to $340.0 million in sales milestone payments) ("Ionis milestones"); (ii) tiered royalties on net sales of Ionis Licensed Products by the Company, its affiliates and sublicensees with a rate based on net sales per calendar year, ranging from a subteen percentage to high teen percentage. The royalties are subject to potential reductions under certain scenarios. In the event that the Company undergoes a change of control prior to receiving regulatory approval from the FDA and are acquired by one of certain top biopharmaceutical or pharmaceutical companies, if the acquisition price exceeds a certain dollar value, the Company will be required to pay Ionis a one-time change of control payment based on the acquisition price, ranging in the low tens of millions of dollars. The payment will accrue interest at a subteen percentage rate per annum, compounded annually, from the date of the Ionis License Agreement through the date such payment is made.

The Company determined that the licenses represent an acquired IPR&D asset that did not have alternative future use as of the acquisition date, and, accordingly, the total amount of the upfront payment of $20.0 million was recognized as R&D expense in the condensed consolidated statement of operations and comprehensive loss for the year ended December 31, 2024. As of June 30, 2026, none of the Ionis milestones had been achieved nor were deemed probable and estimable, and no milestone payments have been made.

License agreements with BMS Co.

In November 2024, the Company entered into a License Agreement with MyoKardia, Inc. ("MyoKardia"), a wholly-owned subsidiary of Bristol-Myers Squibb Company ("BMS Co."), related to Danicamtiv and other compounds (the "Dani Agreement"), and a separate License Agreement with BMS Co. related to KAR-141 (formerly known as BMS-986141) ("Par4") and other compounds (the "Par4 Agreement").

Under the Dani Agreement, the Company received an exclusive, sublicensable (subject to certain conditions and restrictions), royalty-bearing license under certain MyoKardia patents and know-how to develop, manufacture, and commercialize Danicamtiv (formerly known as MYK-491) and certain related compounds (collectively, the "Dani Licensed Compounds") and pharmaceutical products containing such Dani Licensed Compounds (the "Dani Licensed Products") for all human uses worldwide.

As partial consideration for the rights granted to the Company under the Dani Agreement, the Company entered into a Subscription Agreement with MyoKardia pursuant to which the Company issued 1,251,107 shares of Series A Preferred Stock to MyoKardia. As additional consideration for the licenses granted under the Dani Agreement, the Company is required to pay MyoKardia: (i) tiered royalties at a rate based on aggregate annual net sales by the Company, its affiliates and sublicensees of each Dani Licensed Product containing the same Dani Licensed Compound; (ii) a low double-digit percentage of any sublicensing revenue received by the Company, if the Company sublicenses rights under MyoKardia patents or know-how for the development, manufacture or commercialization of any Dani Lead Compound or Dani Lead Compound Licensed Product to a third-party within a certain number of months from the effective date, or November 2026; (iii) up to $42.5 million in the aggregate in development and regulatory milestone payments across all Dani Licensed Products and (iv) up to $265.0 million in sales milestone payments for each of the first two Dani Licensed Products to achieve the applicable sales milestones ((iii) and (iv), collectively, "Dani milestones"). The Company's tiered royalties range from a subteen to high teen percentage of annual net sales of the Dani Licensed Products, subject to potential reductions following the expiration of valid patent claims, due to competition from generic products, for certain third-party license fees, and in the event of a limit on the maximum price as a result of the Inflation Reduction Act of 2022 (the "Inflation Reduction Act"), subject to a customary reduction floor and potential carry forward.

Under the Par4 Agreement, the Company received an exclusive, sublicensable (subject to certain conditions and restrictions), royalty-bearing license under certain BMS Co. patents and know-how to develop, manufacture, and commercialize KAR-141 and certain related compounds thereto (the "Par4 Lead Compounds"), certain back-up compounds and certain related compounds thereto (such compounds, collectively, with the Par4 Lead Compounds, the "Par4 Licensed Compounds", pharmaceutical products containing the Par4 Lead Compounds (the "Par4 Lead Compound Licensed

Products") and pharmaceutical products containing the Par4 Back-Up Compounds (such products, collectively with the Par4 Lead Compound Licensed Products, the "Par4 Licensed Products" for all human uses worldwide.

As partial consideration for the rights granted under the Par4 Agreement, the Company issued 293,469 shares of Series A Preferred Stock. As additional consideration for the licenses granted under the Par4 Agreement, the Company is required to pay BMS Co.: (i) tiered royalties at a rate based on aggregate annual net sales by the Company, its affiliates and sublicensees of each Par4 Licensed Product containing the same Par4 Licensed Compound; (ii) a low double-digit percentage of any sublicensing revenue received by the Company, if the Company sublicenses rights under BMS Co. patents or know-how for the development, manufacture or commercialization of any Par4 Lead Compound or Par4 Lead Compound Licensed Product to a third-party a certain number of months from the effective date, or November 2026; (iii) up to $10.0 million in the aggregate in development and regulatory milestone payments across all Par4 Licensed Products and (iv) up to $265.0 million in sales milestone payments for each of the first two Par4 Licensed Products to achieve the applicable sales milestones ((iii) and (iv), collectively, "Par4 milestones"). The Company's tiered royalties range from a subteen to high teen percentage of annual net sales of the Par4 Licensed Products, subject to potential reductions following the expiration of valid patent claims, due to competition from generic products, for certain third-party license fees, and in the event of a limit on the maximum price as a result of the Inflation Reduction Act, subject to a customary reduction floor and potential carry-forward. Additionally, certain BMS Co. patents and know-how are sublicensed by BMS Co. pursuant to an upstream license agreement with a university and the Company is responsible for reimbursing BMS Co. for certain milestone payments and other amounts payable under such upstream agreement that arise from its development, manufacturing or commercialization activities under the Par4 Agreement. The milestone reimbursement obligations include up to (i) $12.5 million in the aggregate in development and regulatory milestone payments per certain Par4 Licensed Products and (ii) $13.625 million in the aggregate in development and regulatory milestone payments per certain other Par4 Licensed Products.

In connection with the license agreements, the Company issued an aggregate of 1,544,576 shares of Series A Preferred Stock to MyoKardia and BMS Co., including 1,251,107 shares of Series A Preferred Stock under the Dani Agreement, and 293,469 shares of Series A Preferred Stock under Par4 Agreement, at the estimated fair value of $19.10 per share as of issuance date, with a total estimated fair value of $29.5 million.

The Company determined that the Dani and Par4 licenses represent acquired IPR&D assets that did not have alternative future use as of the acquisition date, and, accordingly, an amount of $29.5 million was recognized as R&D expense in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2024.

As of June 30, 2026, none of the Dani milestones or Par4 milestones had been achieved nor were deemed probable or estimable, and no milestone payments have been made.

As part of the Company's initial public offering, all outstanding shares of the Company's redeemable convertible preferred stock converted into an equivalent number of shares of common stock, after giving effect to the forward stock split.

6. Intangible assets

The following table summarizes the intangible assets, net (in thousands):

	June 30, 2026			December 31, 2025		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Finite-lived intangible assets:						
Developed technology	$ 29,829	$ (5,049)	$ 24,780	25,400	(3,024)	22,376
Other	2,215	(577)	1,638	1,165	(316)	849
Total finite-lived intangible assets	32,044	(5,626)	26,418	26,565	(3,340)	23,225
Total intangible assets	$ 32,044	$ (5,626)	$ 26,418	$ 26,565	$ (3,340)	$ 23,225

Developed technology primarily consists of the cardiovascular analytics data platform originally recognized upon acquisition of Prolaio, Inc. during the three months ended June 30, 2025. The developed technology, with a gross carrying amount of $25.4 million, was assigned an estimated useful life of seven years. The acquired IPR&D assets, also recognized upon the Prolaio acquisition, and presented within the other category, were initially classified as indefinite-lived intangible

assets. By December 31, 2025, the Company determined that the underlying projects had reached technological feasibility and accordingly reclassified these assets as finite-lived intangible assets with an estimated useful life of three years.

Subsequent to the Prolaio acquisition, the Company's engineering team continued to enhance the acquired technology and expand the platform capabilities through the addition of new features and functional improvements. The Company capitalizes certain qualifying costs related to the development of computer software for internal use. The Company capitalized internal-use software costs totaling $5.4 million for the six months ended June 30, 2026.

Capitalized internal-use software costs related to the development of the Prolaio platform are included within the developed technology category and amounted to $4.4 million for the six months ended June 30, 2026. Capitalized internal-use software costs related to other development projects are included within the other category, and amounted to $1.0 million for the six months ended June 30, 2026.

As of June 30, 2026, the other finite-lived intangible assets category includes $2.8 million of software development costs related to projects not yet placed in service. No amortization expense was recorded in relation to these costs for the three and six months ended June 30, 2026.

Amortization expense related to finite-lived intangible assets was $1.1 million, $2.2 million for the three and six months ended June 30, 2026, and $1.0 million and $1.3 million for the three and six months ended June 30, 2025, respectively, and was primarily included in R&D expenses on the condensed consolidated statements of operations and comprehensive loss.

The following table summarizes the estimated future amortization expense associated with the finite-lived intangible assets as of June 30, 2026 (in thousands):

	Amount
2026 (six months remaining)	$ 2,237
2027	4,473
2028	4,157
2029	3,953
2030	3,953
Thereafter	4,834
Total estimated future amortization expense	$ 23,607

As of June 30, 2026 and December 31, 2025, there were no accumulated impairment losses related to intangible assets.

7. Leases

The Company leases office and laboratory spaces which are classified as operating leases on the condensed consolidated balance sheets.

Cove Lease

In September 2024, the Company entered into a facility lease in South San Francisco, California (the "Cove Lease"), for approximately 36,000 rentable square feet. The lease commenced in October 2024 and has a contractual term of 66 full calendar months, expiring in April 2030. The Cove Lease includes an option to extend the lease term for an additional five years. At lease commencement, the Company evaluated the renewal option and concluded that it is not reasonably certain that the renewal option will be exercised.

Under the terms of the Cove Lease, the landlord has made available a tenant improvement allowance of up to $0.7 million for qualifying permanent improvements to the leased premises. The allowance is structured as a landlord-funded improvement option that, if utilized, becomes subject to repayment by the Company as additional rent over the remaining lease term at a contractually specified interest rate. As of the reporting date, the Company has not elected to utilize any portion of the allowance, has not incurred any qualifying improvement expenditures, and has not received any landlord-initiated improvements requiring reimbursement. Accordingly, no related adjustments to ROU asset or lease liability have been recognized in the Company's condensed consolidated financial statements.

Princeton Lease

In February 2025, the Company entered into an office space lease for approximately 21,500 square feet in Princeton, New Jersey (the "Princeton Lease"). The lease commenced in September 2025 and has a contractual term of 90 full calendar months, expiring in March 2033. The Princeton Lease includes an option to extend the lease term for an additional five years. At lease commencement, the Company evaluated the renewal option and concluded that it is not reasonably certain that the renewal option will be exercised.

Concurrent with the execution of the Princeton lease, the Company executed a temporary swing-space lease, that provided approximately 9,000 square feet of office space in its 'as is' condition to support business operations while the main premises underwent landlord-performed improvements. The swing-space lease commenced in February 2025 and ended in September 2025 when the Company took possession of the main Princeton Lease premises. The arrangement met the definition of a lease under ASC 842 and qualified as a separate lease, however it met the short-term lease exemption criteria. Accordingly, the Company recognized lease expense for the swing-space as incurred, with no recognition of a ROU asset or lease liability for this arrangement.

The Company maintains letters of credit related to the above leases totaling $0.5 million and $0.5 million as of June 30, 2026 and December 31, 2025, respectively. These lease-related letters of credit are reflected within restricted cash, non-current on the Company's condensed consolidated balance sheets as of June 30, 2026 and December 31, 2025.

The lease expenses, which are included in operating expenses in the condensed consolidated statements of operations and comprehensive loss, were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating lease expense	$ 838	$ 602	$ 1,700	$ 1,187
Variable lease expense	444	342	705	650
Short-term lease expense	5	4	20	64
Total lease expense	$ 1,287	$ 948	$ 2,425	$ 1,901

Supplemental disclosure of cash flow information related to leases was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Cash paid for amounts included in the measurement of lease liabilities	$ 905	$ 30	$ 1,726	$ 40
Right-of-use assets obtained in exchange for new operating lease liabilities	—	—	560	278

As of June 30, 2026 and December 31, 2025, the weighted-average remaining lease term for operating leases was 4.7 years and 5.2 years, respectively, and the weighted-average discount rate was 10.04% and 10.02%, respectively.

The following table reconciles the undiscounted future minimum lease payments required for the operating leases as of June 30, 2026 (in thousands):

	Amount
2026 (six months remaining)	$ 1,939
2027	3,816
2028	3,666
2029	3,644
2030	1,774
Thereafter	1,821
Total minimum lease payments	16,660
Less: imputed interest	(3,313)
Present value of operating lease liabilities	$ 13,347

8. Commitments and contingencies

Research and development agreements

The Company enters into various agreements in the ordinary course of business, such as those with suppliers, clinical research organizations, contract manufacturing organizations, and clinical trial sites. These agreements provide for termination at the request of either party, generally with less than one-year notice and are, therefore, cancellable contracts and, if cancelled, are not anticipated to have a material effect on the Company's financial condition, results of operations, or cash flows.

Legal proceedings

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of business. The Company accrues a liability for such matters when it is probable that the loss has been incurred and the amount of the loss can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. As of June 30, 2026, and December 31, 2025, the Company was not a party to any material legal proceedings. Legal fees are expensed as incurred.

Indemnification

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties.

In accordance with the Company's amended and restated certificate of incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving in such capacity. The Company has not incurred any material indemnification claims to date. The Company maintains directors' and officers' liability insurance, which may reduce its exposure in the event of future claims.

Future milestone and royalty payments

In 2025 and 2024, the Company entered into certain acquisition and licensing agreements. These agreements include potential future milestone payments, royalties and other contingent consideration, payable upon the achievement of specified development, regulatory and commercial milestones. Refer to Note 5, *"Acquisition and Licensing Agreements"*.

9. Redeemable convertible preferred stock

Redeemable convertible preferred stock

The Company had previously issued Series A redeemable convertible preferred stock (the "Series A Preferred Stock"), Series B redeemable convertible preferred stock (the "Series B Preferred Stock") and Series B-1 redeemable convertible preferred stock (the "Series B-1 Preferred Stock"), which are collectively referred to as "Preferred Stock". In connection with the Company's initial public offering, all outstanding shares of the Preferred Stock were converted into an equivalent number of shares of common stock, after giving effect to the forward stock split.

Series A Preferred Stock

In June 2024, the Company entered into a Series A preferred stock purchase agreement (the "Series A SPA") under which it issued and sold 2,487,790 shares of Series A Preferred Stock, at a price of $19.42 per share, for gross cash proceeds of $48.3 million (the "Series A Initial Closing"). Contemporaneously, investors converted their Simple Agreements for Future Equity ("SAFEs") with a principal amount of $0.9 million into 43,762 shares of Series A Preferred Stock, bringing the total number of shares of Series A Preferred Stock issued at the Series A Initial Closing to 2,531,552 shares. An initial additional closing under the Series A SPA occurred in July 2024, at which the Company sold 2,883,206 additional shares of Series A Preferred Stock at a price of $19.42 per share for gross cash proceeds of $56.0 million.

Pursuant to the Series A SPA, the Company had an obligation to issue and certain Series A investors were obligated to purchase additional shares in two additional closings of $100.0 million each, subject to the satisfaction of specified milestone and cash-related conditions. The Second Tranche closing was to be funded upon the Company's successful enrollment of the first patient in a Phase 3 clinical trial of either the Tonlamarsen Product or the Ataciguat Product, whichever occurs first (the "Second Tranche"). The Third Tranche closing was to be funded at the earlier of enrollment of the first patient in a Phase 3 clinical trial or an acquisition of any other clinical-stage pharmaceutical product or compound other than Tonlamarsen Product or Ataciguat Product or compound other than Ataciguat (the "Third Tranche"). Each investor could elect to voluntarily fund their share of the two tranches prior to the achievement of the milestones.

In November 2024, the Company determined, that the conditions related to the Third Tranche had become probable of achievement, subject to meeting the required cash-balance condition. In February 2025, following the satisfaction of the cash-balance condition, the Third Tranche closing was consummated, pursuant to which the Company sold 5,148,587 additional shares of Series A Preferred Stock, resulting in total gross cash proceeds of $100.0 million. In August 2025, the condition applicable to the Second Tranche was waived, and the tranche closed, pursuant to which the Company sold 5,148,587 additional shares of Series A Preferred Stock, resulting in additional gross cash proceeds of $100.0 million.

Preferred stock tranche obligations

Upon the initial closing of the Series A Preferred Stock, with respect to the Second Tranche, the Company recorded a preferred stock tranche obligation liability of $3.2 million, and, with respect to the Third Tranche, the Company recorded a preferred stock tranche liability of $9.2 million. The fair value of the Series A Preferred Stock tranche obligations was allocated from the gross cash proceeds of the Series A Preferred Stock issuance, and the residual value was then allocated to the Series A Preferred Stock.

As of December 31, 2024, the fair value of the Second Tranche obligation was estimated as a liability in an amount of $7.3 million, and the fair value of the Third Tranche was estimated as an asset in an amount of $1.7 million.

In February 2025, upon closing of the Third Tranche, the Company remeasured the preferred stock tranche obligation as of the closing date. The estimated fair value of the preferred stock tranche asset in an amount of $1.7 million was settled and the shares of Series A Preferred Stock issued in the Third Tranche were recorded at fair value on the date of issuance.

As of June 30, 2025, the estimated fair value of the Second Tranche preferred stock tranche liability was $11.2 million. Accordingly, the Company recognized a loss in an amount of $3.9 million which was recorded within change in fair value of preferred stock tranche obligations in its condensed consolidated financial statements. Both the Second and Third Tranches of the Series A Preferred Stock were closed during the year ended December 31, 2025, and accordingly, no change in fair value was recorded for the six months ended June 30, 2026.

Refer to Note 3, "*Fair Value Measurements*" for further details on valuation methodology and assumptions used.

BMS Co. license

In November 2024, in connection with license agreements, the Company issued an aggregate of 1,544,576 shares of Series A Preferred Stock to MyoKardia and BMS Co., at the estimated fair value of $19.10 per share as of issuance date, with a total estimated fair value of $29.5 million. Refer to Note 5, "*Acquisitions and Licensing Agreements*" for more details.

Series B Preferred Stock and Series B-1 Preferred Stock

In September 2025, the Company entered into a Series B preferred stock purchase agreement (the "Series B SPA") under which it issued and sold 4,082,529 shares of Series B Preferred Stock and 2,610,635 shares of Series B-1 Preferred Stock, at a price of $21.37 per share for each series, for gross cash proceeds of $143.0 million (the "Series B Initial Closing"). In addition, the Company issued warrants to purchase 1,752,080 shares of the Company's common stock to certain investors. Refer to Note 10, *"Common Stock"* for more details.

Subsequent to the Series B Initial Closing, the first additional closing occurred on October 9, 2025, at which the Company sold 4,025,257 additional shares of Series B Preferred Stock at the same price of $21.37 per share for gross cash proceeds of $86.0 million. Additionally, the second additional closing was consummated on October 15, 2025, at which the Company sold 1,170,134 additional shares of Series B-1 Preferred Stock at a price of $21.37 per share for gross cash proceeds of $25.0 million.

In March 2026, the Company amended its certificate of incorporation to authorize the issuance of additional shares of Series B Preferred Stock and sold 468,053 shares of Series B Preferred Stock at the original price of $21.37 per share, for gross cash proceeds of $10.0 million. At the closing date, the estimated fair value of the Series B Preferred Stock was $24.36 per share. As additional consideration, the investor agreed to provide the Company with access to certain intellectual property pursuant to a license that was subject to final documentation and expected to be executed within 90 days of the closing date. Based on the stage of negotiations and the Company's existing relationship with the investor, management concluded that execution of the license was probable and that the Company had a present right to future economic benefits at issuance. Accordingly, the Company recorded the issuance of shares of the Series B Preferred Stock at fair value of $11.4 million. The excess of the fair value over the cash proceeds of $1.4 million was initially recorded as an other current asset within prepaid and other current assets on its condensed consolidated balance sheet. The definitive license agreement was executed in June 2026. Upon execution, the Company reassessed the prepaid asset and concluded that the rights received relate to research and development activities; accordingly, the $1.4 million was expensed as research and development costs during the three months ended June 30, 2026.

Summary

Preferred stock as of December 31, 2025 consisted of the following:

Series	Shares authorized	Shares issued and outstanding	Original issue price per share	Aggregate liquidation amount	Net carrying value
Series A Preferred Stock	17,256,508	17,256,508	19.42	335,170	324,544
Series B Preferred Stock	8,482,146	8,482,146	21.37	181,222	180,954
Series B-1 Preferred Stock	3,780,769	3,780,769	21.37	80,776	80,652
Total as of December 31, 2025	29,519,423	29,519,423		$ 597,168	$ 586,150

Immediately prior to the closing of the Company's initial public offering on June 22, 2026, pursuant to the stock split and proportional adjustment reflecting the 1.5928-for-1 conversion ratio, all of the Company's outstanding Preferred Stock was converted into an aggregate of 47,764,024 shares of common stock.

10. Stockholders' Equity

Common Stock

As of June 30, 2026, the Company's certificate of incorporation, as amended and restated on June 22, 2026, authorized the Company to issue 700,000,000 shares of common stock, $0.00001 par value, with 500,000,000 of such shares designated as voting common stock and 200,000,000 of such shares designated as non-voting common stock. As of June 30, 2026, 93,467,940 shares of voting common stock and no shares of non-voting common stock were issued and outstanding. The voting, dividend and liquidation rights of the holders of the Company's common stock may be subject to and qualified by the rights, powers and preferences of the holders of the Company's preferred stock, if issued. Each share of voting common stock is entitled to one vote on all matters submitted to stockholders, except that, pursuant to the Company's certificate of incorporation, holders of common stock are not entitled to vote on amendments to the certificate that relate solely to the terms of the outstanding preferred stock if the holders of such preferred stock are entitled to vote separately on those amendments. Each holder of non-voting common stock shall be treated equally to that of the voting common stock except that the holders thereof shall have no right to vote for the election of directors or on any other matters requiring stockholder action, except as required by law. Each holder of non-voting common stock shall also be entitled to convert such stock to voting common stock, at a 1-to-1 ratio, provided such holder's beneficial ownership, as defined under Section 13(d) of the Exchange Act, does not exceed 9.99% of the shares then outstanding.

Prior to the June 22, 2026 amendment, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 55,133,053 shares of common stock, $0.00001 par value. The voting, dividend and liquidation rights of the holders of the Company's common stock were subject to and qualified by the rights, powers and preferences of the holders of the Company's preferred stock set forth above. Each share of common stock was entitled to one vote on all matters submitted to stockholders, except that, pursuant to the Company's certificate of incorporation, holders of common stock are not entitled to vote on amendments to the certificate that relate solely to the terms of the outstanding preferred stock if the holders of such preferred stock are entitled to vote separately on those amendments.

The holders of common stock are entitled to receive dividends, if any, as declared by the Company's board of directors, subject to the preferential dividend rights of the preferred stock. As of June 30, 2026, and December 31, 2025 no dividends have been declared or paid.

Preferred Stock

As of June 30, 2026, the Company's certificate of incorporation, as amended and restated on June 22, 2026, authorized the Company to issue 10,000,000 shares of undesignated preferred stock, $0.00001 par value. No shares of preferred stock have been issued and no shares were outstanding as of June 30, 2026.

Warrants

In connection with the issuance of Series B Preferred Stock, the Company issued warrants to purchase up to 1,752,080 shares of Company's common stock (the "Warrants") with an exercise price of $13.41 per share, exercisable, in whole or in part, only upon the first date the Company achieves a valuation of $5.0 billion and until the tenth anniversary of the issuance date (September 4, 2035). The warrants, which were classified as equity, were initially recorded at fair value and do not require subsequent remeasurement.

The warrants were granted only to a select group of investors that led the Series B Preferred Stock financing round as an economic incentive for their role. The fair value of the warrants, totaling $7.4 million, was recognized as a warrant issuance expense within the condensed consolidated statement of operations and comprehensive loss in the period of issuance.

The fair value of the warrants was measured using the Monte Carlo pricing model. Significant inputs into the model as of September 4, 2025 were as follows:

		September 4, 2025
Exercise price	$	13.41
Expected liquidity event date		June 6, 2027
Warrant expiration date		September 4, 2035
Common stock IPO threshold price	$	13.41
Interest rate (annual)		4.17%

As of June 30, 2026, no warrants were exercised and all remain outstanding.

11. Stock-based compensation

2023 stock option and grant plan (as amended and restated)

The Company adopted the 2023 Stock Option and Grant Plan (as amended and restated, the "2023 Plan") on August 18, 2023. The 2023 Plan remained in effect until June 17, 2026. The 2023 Plan provided for the grant of incentive stock options, non-qualified stock options, restricted stock awards, unrestricted stock awards and restricted stock units to the employees, directors and consultants of the Company. The option exercise price of each option was determined by the administrator of the 2023 Plan and could not be less than 100% of the fair market value of the Company's common stock on the date of grant, or in the case of an incentive stock option granted to a 10% owner, the exercise price could not be less than 110% of the fair market value of the Company's common stock on the date of grant. The maximum term of the options granted under the 2023 Plan was no more than ten years. Service-based awards generally vest at 25% one year from the vesting commencement date and ratably each month thereafter for a period of 36 months, subject to continuous service. Performance and market-based awards would have individual vesting conditions. The shares of common stock underlying any awards that are forfeited, cancelled, reacquired by the Company prior to vesting, satisfied without the issuance of stock, or otherwise terminated (other than by exercise), or held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding under the 2023 Plan were added back to the shares of common stock available for issuance under the 2023 Plan and, following June 17, 2026, will be added back to the shares of common stock available for issuance under the 2026 Plan.

As of June 30, 2026 and December 31, 2025, the Company had reserved 26,224,708 and 33,752,354 shares of common stock for issuance under the 2023 Plan, respectively. As of June 30, 2026 and December 31, 2025, the number of shares remaining for grant under the 2023 Plan were zero and 4,375,891 shares, respectively.

2026 stock option and incentive plan

The Company adopted the 2026 Stock Option and Incentive Plan (the "2026 Plan") on June 17, 2026, upon the cessation of the 2023 Plan. The 2026 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights ("SARs"), restricted stock awards, restricted stock units, and cash or other stock-based awards to the employees, directors, consultants and other service providers of the Company, provided that incentive stock options may be granted only to employees. The option exercise price of each option will be determined by the administrator of the 2026 Plan and shall not be less than 100% of the fair market value of the Company's common stock on the date of grant, or in the case of an incentive stock option granted to a 10% owner, the exercise price shall not be less than 110% of the fair market value of the Company's common stock on the date of grant. The maximum term of the options granted under the 2026 Plan shall not be more than ten years. Service-based awards generally vest at 25% one year from the vesting commencement date and ratably each month thereafter for a period of 36 months, subject to continuous service. Performance and market-based awards will have individual vesting conditions. Shares subject to 2023 Plan or 2026 Plan awards that are forfeited, cancelled, reacquired by the Company prior to vesting, satisfied without the issuance of stock, or otherwise terminated (other than by exercise), or held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, will be added (or added back) to the shares of common stock available for issuance under the 2026 Plan.

A total of 10,620,000 shares of common stock were initially reserved for issuance under the 2026 Plan, and such reserve will automatically increase on January 1 of each year, beginning January 1, 2027, by the lesser of (i) 5% of the total shares of common stock outstanding (including shares issuable upon exercise of any outstanding pre-funded warrants with a nominal exercise price) as of the immediately preceding December 31, or (ii) a smaller number of shares as determined by the Company's board of directors or compensation committee.

As of June 30, 2026, the Company had reserved 10,620,000 shares of common stock for issuance under the 2026 Plan. As of June 30, 2026, the number of shares remaining for grant under the 2026 Plan were 8,469,613 shares.

2026 employee stock purchase plan

On June 17, 2026, the Company adopted the 2026 Employee Stock Purchase Plan (the "ESPP"), which permits participants to contribute up to 15% of their eligible compensation during defined rolling six-month periods to purchase the Company’s common stock. The purchase price of the shares will be 85% of the lower of the fair market value of the Company’s common stock on the first day of trading of the offering period or on the applicable purchase date.

A total of 1,180,000 shares of common stock were initially reserved for issuance under the ESPP, and such reserve will increase on January 1 of each year, beginning January 1, 2027, by the least of (i) 2,360,000 shares of common stock, (ii) 1% of the shares of common stock outstanding as of the immediately preceding December 31, or (iii) such lesser number of shares as determined by the compensation committee.

As of June 30, 2026, the Company has not issued any shares under the ESPP.

The following table summarizes stock options activity, inclusive of early exercises, for the six months ended June 30, 2026 (in thousands, except per share data and years):

	Number of Options	Weighted average exercise price	Weighted average remaining contractual term	Aggregate Intrinsic value
Outstanding at December 31, 2025	13,025,261	$ 2.74	8.98	$ 39,810
Granted	13,971,473	8.62		
Exercised	(542,484)	2.27		
Forfeited	(828,533)	3.49		
Expired	(8,602)	2.35		
Outstanding at June 30, 2026	25,617,115	$ 5.93	9.11	$ 458,989
Exercisable as of June 30, 2026	9,700,842	$ 3.84	8.55	$ 194,144
Vested and expected to vest at June 30, 2026	25,617,115	$ 5.93	9.11	$ 458,989

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

Performance-based and market-based options

In June 2024, the Company's Chief Executive Officer was granted an early-exercisable non-qualified option to purchase up to 4,277,389 shares of the Company's common stock at a price per share of $1.35. The options vest contingent upon the satisfaction of the service, performance and market conditions. The service condition is satisfied if the optionee maintains continuous service as the Company's Chief Executive Officer through June 6, 2027. The market condition is structured in five tranches, under which certain percentage of the options vest upon the Company achieving market valuation thresholds at specified levels. The performance condition applies only to 932,676 shares and is satisfied upon the occurrence of specified acquisition by a predetermined date. This performance condition has been met upon the closing of the license agreement with BMS (refer to Note 5, "*Acquisitions and Licensing Agreements"*).

In October 2025, the Company's Chief Executive Officer was granted an early-exercisable non-qualified option to purchase up to 1,400,974 shares of the Company's common stock at the price per share of $5.80, with vesting tied to specific service and market conditions. The service condition is satisfied if the optionee maintains continuous service as the Company's Chief Executive Officer through June 6, 2027. The market condition is structured in four tranches, under which certain percentage of the options vest upon the Company achieving market valuation thresholds at specified levels.

In April 2026, the Company's Chief Executive Officer was granted an early-exercisable non-qualified option to purchase up to 7,268,112 shares of the Company's common stock at the price per share of $9.42, with vesting tied to specific service and market conditions. The service condition is satisfied if the optionee maintains continuous service relationship with the Company. The market condition is structured in four tranches, under which certain percentage of the options vest upon the Company achieving market valuation thresholds at specified levels.

The fair value of these awards was determined using a Monte Carlo simulation. The valuation assumptions utilized in the Monte Carlo model are generally consistent with the inputs discussed in the valuation of stock options below, except for volatility ranging from 80.0% to 90.0% and expected term of 9.0 to 10.0 years.

No options vested, and no options were exercised as of and for the six months ended June 30, 2026 and 2025.

Early exercise liability

The Company's equity plans allow for the early exercise of all stock options granted if authorized by the Company's board of directors at the time of grant. Any shares of common stock issued from the early exercise of stock options are restricted and vest over time. The Company has the option to repurchase any unvested shares at the lower of the original issue price or current fair value upon any voluntary or involuntary termination of such optionee. For accounting purposes, the early exercise of options is not considered to be a substantive exercise until the underlying awards vest and are not considered to be outstanding until those shares vest. The early-exercise liability is included within other non-current liabilities on the condensed consolidated balance sheets.

As of June 30, 2026 and December 31, 2025, unvested shares issued under early exercise provisions and subject to repurchase by the Company totaled 953,572 and 1,173,066, respectively, with related liabilities of $1.4 million and $1.7 million, respectively, included in other non-current liabilities.

Restricted stock activity

The Company's equity plans allow for the grant of restricted stock awards and restricted stock units to certain employees, executives, non-employee scientific advisors, and third-party service providers. The restrictions lapse over time primarily according to service-based vesting conditions of each award. In the event of a voluntary or involuntary termination of the holder's continuous provision of services to the Company, any unvested portion of the restricted stock award is automatically forfeited.

The following table summarizes restricted stock activity for the six months ended June 30, 2026:

	Shares of Restricted Stock Awards	Weighted Average Grant date FV	Shares of Restricted Stock Units	Weighted Average Grant date FV
Unvested restricted stock as of December 31, 2025	995,506	$ 5.20	—	$ —
Granted			2,205,481	15.77
Vested	(331,831)	5.20	(19,684)	9.42
Forfeited			—	—
Unvested restricted stock as of June 30, 2026	663,675	$ 5.20	2,185,797	$ 15.82

During six months ended June 30, 2026, the Company granted a total of 2,205,481 restricted stock units, including 78,748 restricted stock units subject to both service-based and performance-based vesting conditions (the performance condition was satisfied upon the Company's IPO in June 2026), and 2,126,733 restricted stock units granted to certain employees and directors that vest in full on the two-year anniversary of the grant date, subject in each case to the applicable continued service relationship through the vesting date.

Modification of Chief Medical Officer Restricted Stock Award

The original vesting terms of the Chief Medical Officer's award of 3,982,000 shares granted in August 2023 provided for 80% of the shares to vest immediately, with the remaining 20% vesting in equal monthly installments over a 24-month period.

On June 6, 2024, in connection with the Company's Series A financing and adoption of the 2023 Plan, the Company revised the vesting terms of the award to provide for 50% immediate vesting, with the remaining 50% vesting monthly over 36 months from the new vesting commencement date. The Company determined that this was an escrowed share arrangement under ASC 718 and determined that the shares were a new compensatory award. The incremental compensation cost of $7.8 million was measured as the excess of the fair value of the modified award over the fair value of the original award immediately prior to modification, to be recognized over a 36-month service period starting on June 6, 2024. For purposes of the net loss per share calculation, the Company determined that the modification is equivalent to a reverse stock split and, accordingly, adjusted the weighted-average number of unvested restricted stock shares under the Chief Medical Officer's award as if those terms had been in effect for all periods presented.

Stock-based compensation expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development	$ 3,434	$ 4,605	$ 5,766	$ 5,841
General and administrative	8,261	14,046	11,287	15,748
Total stock-based compensation expense	$ 11,695	$ 18,651	$ 17,053	$ 21,589

As of June 30, 2026, unrecognized stock-based compensation expense related to unvested awards totaled $159.2 million, which is expected to be recognized over a weighted-average period of 2.72 years.

12. Income taxes

The Company determines its income tax provision for interim periods using an estimate of its annual effective tax rate, adjusted for discrete items occurring in the periods presented.

The Company recorded no income tax expense or benefit for the three months ended June 30, 2026 and 2025, representing effective tax rates of 0.0% for both periods. The Company recorded no income tax expense and an income tax benefit of $4.2 million for the six months ended June 30, 2026 and 2025, representing effective tax rates of 0.0% and 5.2%, respectively.

There was no change in income tax expense or benefit for the three months ended June 30, 2026 as compared to the three months ended June 30, 2025.

For the six months ended June 30, 2026, as compared to the six months ended June 30, 2025, the change from an income tax benefit to income tax expense was primarily due to a discrete release of valuation allowance in the prior-year period attributable to deferred tax liabilities acquired in a business combination, which provided a source of future taxable income supporting realization of a portion of the Company's existing deferred tax assets.

For the three and six months ended June 30, 2026, the effective tax rate differs from the U.S. federal statutory rate primarily because the Company maintains a full valuation allowance against its net deferred tax assets, as the Company has determined that realization of those assets is not more likely than not based on available evidence.

The Company had no material unrecognized tax benefits as of June 30, 2026.

13. Net loss per share

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 June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Numerator:				
Net loss - basic and diluted	$ (116,236)	$ (57,445)	$ (172,307)	$ (75,464)
Denominator:				
Weighted-average number of shares of common stock outstanding	26,914,705	16,119,196	21,751,721	16,111,246
Less: Weighted-average number of shares of common stock subject to repurchase	(990,398)	(1,756,313)	(1,044,927)	(1,754,208)
Less: Weighted-average number of shares of unvested restricted common stock	(728,095)	(1,982,495)	(810,645)	(2,313,060)
Weighted-average number of shares of common stock outstanding - basic and diluted	25,196,212	12,380,388	19,896,149	12,043,978
Net loss per share - basic and diluted	$ (4.61)	$ (4.64)	$ (8.66)	$ (6.27)

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding because such securities have an anti-dilutive effect due to the Company's net loss, in common stock equivalent shares:

	As of June 30,	
	2026	2025
Redeemable convertible preferred stock	—	19,285,484
Shares subject to outstanding stock options	25,501,973	11,160,711
Shares subject to outstanding common stock warrants	1,752,080	—
Unvested exercised options subject to repurchase	953,572	1,772,353
Unvested restricted stock awards	663,675	1,659,170
Unvested restricted stock units	2,185,797	—
Total	31,057,097	33,877,718

14. Segment reporting

The Company views its operations and manages its business as one operating segment, focused on the discovery and development of novel cardiovascular drugs for the treatment of heart diseases.

The CODM, is responsible for making decisions regarding resource allocation and assessing performance. The Company's CODM is its Chief Executive Officer. No revenue has been generated since inception, and all assets are held in the United States.

The CODM assesses performance of the business, monitors budget versus actual results and manages and allocates resources to the Company's operations using condensed consolidated net loss as the primary measurement. The CODM is regularly provided with entity-wide expense categories that are largely consistent with those found on the Company's condensed consolidated statements of operations and comprehensive loss. The measure of segment assets is reported on the condensed consolidated balance sheets as total consolidated assets.

The table below is a summary of the segment loss, including significant segment expenses (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Program expenses:				
Danicamtiv	$ 13,228	$ 884	$ 23,555	$ 884
Ataciguat	7,975	7,889	16,617	9,834
Tonlamarsen	3,925	4,744	7,870	8,408
Research and development - compensation and benefits *	18,505	14,801	32,293	22,450
Research and development - other	12,732	7,521	21,097	13,037
Total Research and development expense	56,365	35,839	101,432	54,613
General and administrative expense - compensation and benefits *	13,516	16,995	21,420	20,949
General and administrative expense - other	5,351	4,291	11,090	7,641
Total general and administrative expense	18,867	21,286	32,510	28,590
Change in fair value of contingent milestone liabilities	43,529	—	43,529	—
Total operating expense	118,761	57,125	177,471	83,203
Other income/expense **	(2,525)	320	(5,164)	(3,572)
Loss before income taxes	$ 116,236	$ 57,445	$ 172,307	$ 79,631

* Includes stock-based compensation expense

** Other income (expense) for the three and six months ended June 30, 2026 primarily includes interest income. Other income (expense) for the six months ended June 30, 2025 primarily includes bargain purchase gain, change in fair value of Series A Preferred Stock tranche obligations and interest income.

15. Related party transactions

Prolaio transactions

On February 24, 2025, the Company acquired 100% of the outstanding shares of Prolaio, Inc. At the time of the acquisition, Tassos Gianakakos, the Company's Chief Executive Officer and member of its board of directors, also served as Prolaio, Inc.'s Chief Executive Officer and as a member of its board of directors and Jay Edelberg, the Company's Chief Medical Officer, served as its Head of Research & Development and as a member of its board of directors. Mr. Gianakakos and Dr. Edelberg beneficially owned 55.7% and 17.1%, respectively, of Prolaio, Inc. at the time of its acquisition. Accordingly, Prolaio, Inc. was considered a related party during the pre-acquisition period, and the Prolaio acquisition itself constituted a related-party transaction. In addition, the amendment to the Agreement and Plan of Merger entered into on May 1, 2026 with the former Prolaio stockholders also constituted a related-party transaction. Refer to Note 5, "*Acquisitions and Licensing Agreements*" for additional information.

During the pre-acquisition period, Prolaio, Inc. provided services to the Company utilizing its proprietary device, data monitoring, and analytics platform in support of the development of the Company's cardiovascular product candidates.

For the period from January 1, 2025 through February 24, 2025 (the respective acquisition date), the Company made a prepayment of $0.3 million, and recognized $0.3 million of expense related to services performed by Prolaio, Inc. The Company had a prepaid expense balance of $0.3 million as of the acquisition date. Subsequent balances and transactions between Prolaio, Inc. and the Company are eliminated at consolidated level.

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 in conjunction with our unaudited condensed consolidated financial statements and related notes and other financial information included in Part I of this Quarterly Report on Form 10-Q as well as our audited consolidated financial statements and related notes for the year ended December 31, 2025 included in our final prospectus dated June 17, 2026 filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act of 1933, as amended. This discussion and analysis and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, strategies, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. You should carefully read the section titled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

Overview

We are a clinical-stage precision therapeutics company developing medicines that target the root cause of specific cardiovascular diseases where no approved treatments exist. Our mission is to develop multiple targeted cardiovascular treatments in parallel that bring people with cardiovascular diseases closer to the cures they deserve. Our team is values-based and mission-driven, led by a proven and experienced management team applying a new philosophy to cardiovascular drug development. We have three late-stage programs, Danicamtiv, Ataciguat, and Tonlamarsen, in clinical development for indications for which no approved therapies currently exist. These programs are designed to create new standards of care for high-need patients.

Our management team, including leaders from MyoKardia, Inc. ("MyoKardia"), has deep-domain knowledge of, and proven ability to, navigate the complexity of cardiovascular disease and translate that insight into an innovative drug development approach, enhanced by proprietary data and analytics technology through our Prolaio platform, to deliver with exceptional speed and execution. We believe this uniquely enables us to apply a high degree of precision to cardiovascular drug development, targeting the root causes of disease, rather than later onset cardiovascular symptoms. By applying our differentiated understanding of cardiovascular clinical endpoints, prioritizing indications with high regulatory clarity and significant unmet need, and focusing on biology-led patient selection for our trials, we believe we are uniquely positioned to maximize our probability of clinical success and efficiently develop and deliver multiple novel medicines with the greatest possible therapeutic impact for patients and healthcare providers alike.

Cardiovascular disease is the leading cause of death worldwide, yet innovation has lagged due to drug development focused on broad, downstream, symptom-focused approaches despite disease heterogeneity and genetic variability. Furthermore, clinical trial design has depended on infrequent in-office measurements, failing to capture between visit changes that are critical to understanding cardiovascular disease, including symptoms and variability over time. These factors often result in development requiring lengthy, large and expensive outcomes trials with modest treatment effects. Kardigan's approach is designed to address these challenges through differentiated clinical trial designs with near real-time continuous data collection that enable more modern and efficient development, including reduced enrollment size and trial duration relative to traditional cardiovascular outcomes trials. The intended result is faster and more cost-effective trials designed to achieve a higher probability of success, although there is no guarantee that these results will be achieved.

Our mission is to apply Kardigan's purpose-built cardiovascular development model to advance multiple late-stage programs in parallel, targeting "3 in 4"—three high-impact medicines through pivotal studies in roughly four years, subject to regulatory approval—enabling a credible, standalone and attractive value–creation path. By executing with discipline across portfolio selection, development strategy and trial execution, we aim to deliver better patient outcomes and build a durable, fully integrated, leading cardiovascular-focused biotechnology company.

Our three late-stage programs include Danicamtiv, which we are developing for the treatment of genetic dilated cardiomyopathy ("DCM"), Ataciguat, which is aimed at slowing the progression of calcific aortic valve stenosis ("CAVS") in patients with moderate disease, and Tonlamarsen, which we are developing for the management of blood pressure ("BP") in acute severe hypertension ("ASH") post-hospitalization. Each of these medicines is designed specifically for well-defined patient populations with well-defined regulatory pathways. In the second quarter, we randomized the first patient in the KARDINAL-ASH Phase 2 clinical trial that is evaluating Tonlamarsen for the management of blood pressure in acute severe hypertension ("ASH") post-hospitalization. Additionally, in July, we completed enrollment of Cohort 1 (myosin heavy chain

7, MYH7, and titin, TTN, patients) of the Phase 2b KINSHIP-DCM clinical trial and enrollment of the Phase 3 portion is now underway. We expect to report clinical data from our three late-stage programs in the first half of 2027: Danicamtiv Phase 2b topline data from the KINSHIP-DCM trial, Ataciguat Phase 2b topline data (interim 24-week analysis) from the KATALYST-AV trial and Tonlamarsen Phase 2 topline data in the KARDINAL-ASH trial.

Since our inception, we have not generated any revenue from product sales or other sources and have incurred significant operating losses and negative cash flows from our operations. Our primary uses of cash to date have been conducting research and development, acquisitions, building infrastructure, developing intellectual property, hiring personnel and providing general and administrative support for our expanding operations. To date, we have funded our operations primarily through private placements of our redeemable convertible preferred stock and, most recently, through the net proceeds from our initial public offering ("IPO").

We have incurred operating losses since our inception. Our net losses were $172.3 million and $75.5 million for the six months ended June 30, 2026 and 2025, respectively. As of June 30, 2026, we had an accumulated deficit of $453.4 million. Our operating results also reflect significant period-over-period and year-over-year increases in research and development and general and administrative expenses, driven by the progression of our therapeutic programs, increased headcount, integration of acquired assets, and expanded clinical and operational activities. We expect our expenses and operating losses will increase substantially as we advance our three late-stage candidates clinical development and seek regulatory approvals, manufacture drug product and drug supply, maintain and expand our intellectual property portfolio, as well as hire additional personnel, pay for further accounting, audit, legal, regulatory and consulting services, and pay costs associated with director and officer liability insurance, investor and public relations activities and other expenses associated with operating as a public company.

In addition, we have preclinical and clinical development, regulatory and commercial milestone payment obligations under our licensing arrangements. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our preclinical studies and our ongoing and planned clinical trials and our expenditures on other research and development activities. Furthermore, we expect to incur additional costs associated with operating as a public company.

On June 22, 2026, we completed our IPO and issued 28,750,000 shares of common stock, including 3,750,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price of $16.00 per share. In connection with the IPO, we received net proceeds of $422.4 million, after deducting $32.2 million in underwriting discounts and commissions, and $5.4 million in other offering costs.

As of June 30, 2026, we had cash, cash equivalents and investments of $660.7 million. Based on our current operating plan, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our operations for at least the next 12 months from the date of this Quarterly Report on Form 10-Q. See the section titled "*—Liquidity and Capital Resources*."

We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our current or future product candidates, which will not be for at least the next several years, if ever. If we obtain regulatory approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, until such time as we can generate significant revenue from sales of our current or future product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. See the section titled "*—Liquidity and Capital Resources*." However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market current or future product candidates that we would otherwise prefer to develop and market ourselves.

Components of results of operations

Revenue

We currently have no products approved for sale, and we have not generated any revenue to date. In the future, we may generate revenue from collaboration or license agreements we may enter into with respect to our current or future product candidates, as well as product sales from any approved product, which approval we do not expect to occur for at least the next several years, if ever. Our ability to generate product revenue will depend on the successful development and eventual commercialization of any current or future product candidates we may pursue. If we fail to complete preclinical and clinical development of our current or future product candidates or obtain regulatory approval for them, our ability to generate future revenues and our results of operations and financial position would be adversely affected.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of internal and external costs associated with our research and development activities, our discovery and research efforts and the preclinical and clinical development of our current and future product candidates. In particular, our research and development expenses include personnel-related costs, including stock-based compensation for employees engaged in research and development functions, manufacturing costs for our product candidates, including fees paid to contract manufacturing organizations ("CMOs"), expenses incurred under arrangements with third parties such as contract research organizations ("CROs"), costs associated with developing and validating our manufacturing process for use in our preclinical studies and ongoing and future clinical trials, costs incurred to obtain licenses to intellectual property and any future payments related to development or regulatory milestones thereto, expenses related to compliance with regulatory requirements and the research and development of our Prolaio platform, internal research and development preclinical costs, and direct and allocated overhead costs for laboratory supplies, research materials, reagents, facility costs, depreciation and other expenses.

We expense research and development costs as incurred. Non-refundable advance payments for future research and development services are recorded as prepaid expenses and recognized as the related goods are delivered or the services are performed. We record accruals for research costs based on estimates of work performed, invoices received and contracted costs, updating these estimates as additional information becomes available from our third-party service providers.

A significant portion of our research and development costs are external costs, which we track on a product candidate-by-product candidate basis once a preclinical asset is designated as a product candidate. Due to our ability to use certain resources across several programs, personnel-related expenses and indirect or shared operating costs incurred for our research and development programs are not recorded or maintained on a product candidate-by-product candidate basis.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to conduct our ongoing research and development activities, expand our pipeline, advance our preclinical research programs toward clinical development and conduct our current and planned clinical trials. The timing and amount of these expenses are inherently difficult to predict, and we make funding determinations for each program on an ongoing basis based on preclinical and clinical results, regulatory developments and ongoing assessments of each program's commercial potential.

Our future development costs may vary significantly depending on the scope, timing and outcome of clinical development and regulatory review for Danicamtiv, Ataciguat, Tonlamarsen and any future product candidates, our ability to maintain or establish CMO and other third-party arrangements, milestone and collaboration-based payments, and the costs of developing our Prolaio platform. For example, if the FDA, the European Medicines Agency (the "EMA") or another regulatory authority were to require clinical trials beyond those we currently anticipate, or if we experience significant delays in patient enrollment, we would be required to expend significant additional financial resources and time on the completion of clinical development.

General and administrative expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits and stock-based compensation charges for those individuals in executive, legal, finance, human resources, facility operations and other administrative functions. Other significant costs include legal fees relating to intellectual property and corporate matters, professional fees for auditing, accounting, tax and consulting services, office and information technology costs, insurance costs, and facilities, depreciation and other general and administrative expenses, which include direct or allocated expenses for rent and maintenance of facilities and utilities.

We anticipate that our general and administrative expenses will increase for the foreseeable future to support our increased research, development and commercialization activities. These increases will likely include costs related to the hiring of additional personnel and fees paid to outside consultants, pre-launch costs and regulatory filing fees, among other expenses. We also anticipate increased expenses related to audit, accounting, legal, regulatory and tax-related services associated with maintaining compliance with the stock exchange and SEC requirements, director and officer insurance premiums and investor relations costs associated with operating as a public company.

Change in fair value of contingent milestone liabilities

Change in fair value of contingent milestone liabilities reflects the remeasurement of potential future payments due upon our achievement of specified market valuation thresholds within defined contractual periods. These obligations are recorded as liabilities at fair value and remeasured each reporting period, with changes in fair value recognized in our condensed consolidated statements of operations and comprehensive loss. This measurement relies on estimates, including the probability and timing of milestone achievement and expected future Company valuations, and may fluctuate significantly as these estimates and market conditions change.

Other income (expense)

Other income (expense) primarily consists of interest income generated from interest bearing cash, cash equivalents and investments, change in fair value associated with the financial instruments, and various income or expense items. These amounts may fluctuate significantly from period to period due to changes in market conditions, interest rates, the timing of financing transactions, and the remeasurement of instruments carried at fair value, and therefore may not be indicative of future results.

Income tax benefit

Since we generally establish a full valuation allowance against our deferred tax balances, our income tax benefit primarily consists of tax impacts of our deferred income tax assessments resulting from our acquisitions.

Results of operations

Comparison of the three months ended June 30, 2026 and 2025:

The following table summarizes our results of operations for the periods presented (in thousands):

	Three Months Ended June 30,		Change	
	2026	2025	$	%
Operating expenses:				
Research and development	$ 56,365	$ 35,839	$ 20,526	57%
General and administrative	18,867	21,286	(2,419)	(11%)
Change in fair value of contingent milestone liabilities	43,529	—	43,529	100%
Total operating expenses	118,761	57,125	61,636	108%
Loss from operations	(118,761)	(57,125)	(61,636)	108%
Other income (expense):				
Interest income	2,765	1,068	1,697	159%
Change in fair value of preferred stock tranche obligations	—	(1,341)	1,341	(100%)
Other expense, net	(240)	(47)	(193)	411%
Loss before income taxes	(116,236)	(57,445)	(58,791)	102%
Income tax benefit	—	—	—	100%
Net loss	$ (116,236)	$ (57,445)	$ (58,791)	102%

Research and development expenses

The following table summarizes our research and development expenses for the periods presented (in thousands):

	Three Months Ended June 30,		Change	
	2026	2025	$	%
Program expenses:				
Danicamtiv	$ 13,228	$ 884	$ 12,344	1396%
Ataciguat	7,975	7,889	86	1%
Tonlamarsen	3,925	4,744	(819)	(17%)
Research and development - compensation and benefits	18,505	14,801	3,704	25%
Research and development - other	12,732	7,521	5,211	69%
Total Research and development expense	$ 56,365	$ 35,839	$ 20,526	57%

Research and development expenses were $56.4 million for the three months ended June 30, 2026, compared to $35.8 million for the three months ended June 30, 2025, representing an increase of $20.6 million period over period. This increase was primarily driven by an increase in total program expenses, reflecting expanded clinical activity across our pipeline. Danicamtiv program expenses increased by $12.3 million, reflecting the initiation of the Phase 2b/3 clinical trial in October 2025. Ataciguat and Tonlamarsen programs spending was relatively flat, as development activities continued at a consistent level.

In addition to program expenses, our compensation and benefits expenses for personnel engaged in research and development efforts increased by $3.7 million, largely attributable to the headcount growth supporting our expanding research and development operations. The remaining $5.2 million increase in other research and development expenses mainly consisted of $2.5 million of higher outside consulting costs and $1.4 million of acquired IPR&D expense.

General and administrative expenses

General and administrative expenses were $18.9 million for the three months ended June 30, 2026, compared to $21.3 million for the three months ended June 30, 2025, representing a decrease of $2.4 million period over period. The decrease was primarily driven by one-time stock-based compensation expense related to integration bonus of $11.7 million recognized in general and administrative expenses for three months ended June 30, 2025, offset by $8.2 million of higher personnel-related costs and $1.1 million of higher other expenses, including professional services, insurance, facilities-related costs and other corporate overhead.

Change in fair value of contingent milestone liabilities

Change in fair value of contingent milestone liabilities was $43.5 million for the three months ended June 30, 2026, primarily driven by the increase in our market valuation following the completion of our IPO in June 2026, which increased the probability of achieving our market valuation thresholds underlying the amended milestones. No change in fair value of contingent milestone liabilities was recognized for the three months ended June 30, 2025.

Interest income

Interest income was $2.8 million for the three months ended June 30, 2026, compared to $1.1 million for the three months ended June 30, 2025. The increase of $1.7 million period over period was primarily attributable to higher average balances of cash, cash equivalents and investments following the proceeds from our initial public offering and from redeemable convertible preferred stock issuances completed after June 30, 2025.

Change in fair value of preferred stock tranche obligations

Change in fair value of Series A redeemable convertible preferred stock tranche obligations was a loss of $1.3 million for the three months ended June 30, 2025, related to the remeasurement of the Second Tranche obligation prior to its closing. The Second Tranche of the Series A Preferred Stock closed in August 2025, and accordingly, no change in fair value was recorded for the three months ended June 30, 2026.

Comparison of the six months ended June 30, 2026 and 2025:

The following table summarizes our results of operations for the periods presented (in thousands):

	Six Months Ended June 30,		Change	
	2026	2025	$	%
Operating expenses:				
Research and development	$ 101,432	$ 54,613	$ 46,819	86%
General and administrative	32,510	28,590	3,920	14%
Change in fair value of contingent milestone liabilities	43,529	—	43,529	100%
Total operating expenses	177,471	83,203	94,268	113%
Loss from operations	(177,471)	(83,203)	(94,268)	113%
Other income (expense):				
Interest income	5,558	1,900	3,658	193%
Change in fair value of preferred stock tranche obligations	—	(3,912)	3,912	(100%)
Bargain purchase gain	—	5,232	(5,232)	(100%)
Other expense, net	(394)	352	(746)	(212%)
Loss before income taxes	(172,307)	(79,631)	(92,676)	116%
Income tax benefit	—	4,167	(4,167)	(100%)
Net loss	$ (172,307)	$ (75,464)	$ (96,843)	128%

Research and development expenses

The following table summarizes our research and development expenses for the periods presented (in thousands):

	Six Months Ended June 30,		Change	
	2026	2025	$	%
Program expenses:				
Danicamtiv	$ 23,555	$ 884	$ 22,671	2565%
Ataciguat	16,617	9,834	6,783	69%
Tonlamarsen	7,870	8,408	(538)	(6%)
Research and development - compensation and benefits	32,293	22,450	9,843	44%
Research and development - other	21,097	13,037	8,060	62%
Total Research and development expense	$ 101,432	$ 54,613	$ 46,819	86%

Research and development expenses were $101.4 million for the six months ended June 30, 2026, compared to $54.6 million for the six months ended June 30, 2025, representing an increase of $46.8 million period over period. This increase was primarily driven by an increase in total program expenses, reflecting expanded clinical activity across our pipeline. Ataciguat program expenses increased by $6.8 million, primarily due to the initiation and ramp-up of the Phase 2b clinical trial commencing in June 2025. Danicamtiv program expenses increased by $22.7 million, reflecting the initiation of the Phase 2b/3 clinical trial in October 2025. Tonlamarsen program spending was relatively flat, as development activities continued at a consistent level.

In addition to program expenses, our compensation and benefits expenses for personnel engaged in research and development efforts increased by $9.8 million, largely attributable to the headcount growth supporting our expanding research and development operations. The remaining $8.0 million increase in other research and development expenses mainly consisted of $4.0 million of higher outside consulting costs, $2.5 million of higher facilities costs, $1.7 million of additional depreciation and amortization expenses.

General and administrative expenses

General and administrative expenses were $32.5 million for the six months ended June 30, 2026, compared to $28.6 million for the six months ended June 30, 2025, representing an increase of $3.9 million period over period. The increase was primarily driven by $12.2 million of higher personnel-related costs and $3.4 million of higher other expenses, including professional services, insurance, facilities-related costs and other corporate overhead, offset by one-time stock-based compensation expense related to integration bonus of $11.7 million recognized in general and administrative expenses for three months ended June 30, 2025.

Change in fair value of contingent milestone liabilities

Change in fair value of contingent milestone liabilities was $43.5 million for the six months ended June 30, 2026, primarily driven by the increase in our market valuation following the completion of our IPO in June 2026, which increased the probability of achieving our market valuation thresholds underlying the amended milestones. No change in fair value of contingent milestone liabilities was recognized for the six months ended June 30, 2025.

Interest income

Interest income was $5.6 million for the six months ended June 30, 2026, compared to $1.9 million for the six months ended June 30, 2025. The increase of $3.7 million period over period was primarily attributable to higher average balances of cash, cash equivalents and investments following the proceeds from our initial public offering and redeemable convertible preferred stock issuances completed after June 30, 2025.

Change in fair value of preferred stock tranche obligations

Change in fair value of Series A redeemable convertible preferred stock tranche obligations was a loss of $3.9 million for the six months ended June 30, 2025, related to the remeasurement of the Second Tranche obligation prior to its closing. The Second Tranche of the Series A Preferred Stock was closed in August 2025, and accordingly, no change in fair value was recorded for the six months ended June 30, 2026.

Bargain purchase gain

The bargain purchase gain of $5.2 million for the six months ended June 30, 2025 was related to the bargain purchase gain recognized upon the acquisition of Prolaio, Inc. in February 2025.

Income tax benefit

In the six months ended June 30, 2025, we recorded an income tax benefit of $4.2 million due to deferred tax liabilities assumed in connection with our acquisition of Prolaio, Inc., which supported the realizability of our deferred tax assets and resulted in a partial release of our valuation allowance.

Liquidity and capital resources

Sources of liquidity

Since our inception, we have incurred significant operating losses and negative cash flows from operations. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our pipeline and develop our Prolaio platform. Since the completion of our IPO, we have incurred, and expect to incur additional costs associated with operating as a public company. We have funded our operations to date principally through private placements of our redeemable convertible preferred stock and, most recently, through the net proceeds of our IPO. From our inception through June 30, 2026, we have received aggregate gross proceeds of $568.3 million from the sale of our redeemable convertible preferred stock in private placements. On June 22, 2026, we completed our IPO and issued 28,750,000 shares of common stock, including 3,750,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price of $16.00 per share. In connection with the IPO, we received net proceeds of $422.4 million, after deducting $32.2 million in underwriting discounts and commissions, and $5.4 million in other offering costs. We have not generated any revenue or received cost-sharing payments under collaboration or licensing agreements.

Future funding requirements

As of June 30, 2026, we had cash, cash equivalents and investments of $660.7 million. Based on our current operating plan, we believe that our existing resources will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the date of issuance of the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. Our forecast for the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties and actual results could vary materially. Additionally, the process of conducting preclinical studies and testing product candidates in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain. We will need to raise substantial additional capital in the future.

Our future capital requirements will depend on many factors, including but not limited to:

- the type, number, scope, progress, expansions, results, costs and timing of, discovery, preclinical studies and clinical trials of our current and future product candidates;
- the costs associated with maintaining, improving and developing our Prolaio platform;
- the costs and timing of manufacturing for our current and future product candidates and commercial manufacturing;
- the costs, timing and outcome of regulatory review of our current and future product candidates;
- the terms and timing of establishing and maintaining licenses and other similar arrangements;
- the legal costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company;
- the costs associated with hiring additional personnel and consultants as our preclinical and potential future clinical activities increase;
- the costs and timing of establishing or securing sales and marketing capabilities if any current and future product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products; and
- costs associated with any products or technologies that we may in-license or acquire.

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

Cash flows

Comparison of the six months ended June 30, 2026 and 2025

The following table sets forth a summary of the net cash flow activity for the six months ended June 30, 2026 and 2025 (in thousands):

	Six Months Ended June 30,	
	2026	2025
Net cash used in operating activities	$ (107,327)	$ (52,775)
Net cash used in investing activities	(54,892)	(6,563)
Net cash provided by financing activities	437,235	100,184
Net increase in cash, cash equivalents and restricted cash	$ 275,016	$ 40,846

Operating activities

For the six months ended June 30, 2026, net cash used in operating activities was $107.3 million, compared to $52.8 million for the six months ended June 30, 2025. The $54.5 million increase in operating cash usage primarily reflects our expanded operating scale, continued advancement of our development portfolio and organizational growth to support these initiatives.

Net cash used in operating activities for the six months ended June 30, 2026 was $107.3 million, primarily driven by our net loss of $172.3 million partially offset by adjustments to the net loss totaling $61.9 million. The adjustments to the net loss included change in fair value of contingent milestone liabilities of $43.5 million, stock-based compensation expense of $17.1 million, depreciation and amortization expense of $3.2 million, acquired IPR&D expense of $1.4 million and amortization of right-of-use assets of $1.1 million, partially offset by amortization of premiums and accretion of discounts on investments by $1.8 million and other non-cash charges of $2.6 million. Operating cash flows were further impacted by $3.1 million of net cash inflows due to changes in operating assets and liabilities.

Net cash used in operating activities for the six months ended June 30, 2025, was $52.8 million, primarily driven by our net loss of $75.5 million partially offset by adjustments to the net loss totaling $18.3 million. The adjustments to the net loss included non-cash charges of $14.4 million related to integration bonus expense, $7.2 million related to stock-based compensation expense, and $3.9 million related to the change in fair value of preferred stock tranche obligations, and non-cash gains, including bargain purchase gain of $5.2 million and deferred income tax benefit of $4.2 million. Changes in operating assets and liabilities resulted in an additional $4.4 million in net cash inflows.

Investing activities

Net cash used in investing activities was $54.9 million for the six months ended June 30, 2026, compared to $6.6 million net cash used in investing activities for the six months ended June 30, 2025.

Cash used in investing activities for the six months ended June 30, 2026 consisted primarily of $50.0 million of net purchases of investments, partially offset by $2.8 million of capitalized software development costs and $2.1 million used to purchase property and equipment to support the expansion of our laboratory, and corporate infrastructure.

For the six months ended June 30, 2025, net cash used in investing activities was $6.6 million, primarily reflecting the cash portion of the consideration paid for the acquisition of Prolaio, Inc. of $4.0 million and $2.6 million used to purchase property and equipment.

Financing activities

Net cash provided by financing activities was $437.2 million for the six months ended June 30, 2026, compared to $100.2 million for the six months ended June 30, 2025. Financing activities for the six months ended June 30, 2026 consisted primarily of IPO proceeds of $427.8 million, net of underwriters' commissions, $1.8 million of offering costs paid, and $10.0 million of proceeds from issuance of preferred stock. For the six months ended June 30, 2025, financing activities consisted primarily of $100.0 million from issuance of preferred stock, net of issuance costs.

Contractual obligations and commitments

Leases

We lease office space in South San Francisco, California under an operating lease that expires in April 2030 and lease office space in Princeton, New Jersey under an operating lease that expires in March 2033. See Note 7, "*Leases*" in our unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for more information on our lease obligations.

Purchase and other obligations

We enter into contracts in the normal course of business with third-party CROs, CMOs and other third-party vendors for preclinical, clinical trials and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation generally consist of payments for services provided or expenses incurred up to the date of cancellation, including non-cancelable obligations of our service providers and, in some cases, wind-down costs. For further information regarding certain of our license agreements and amounts that could become payable in the future under those agreements, please see Note 8, "*Commitments and Contingencies*" in our unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Merger agreements

Acquisition of Prolaio, Inc.

On February 24, 2025, we entered into an Agreement and Plan of Merger (the "Original Prolaio Merger Agreement"), as amended by Amendment No. 1 (as defined below) (together, the "Amended Prolaio Merger Agreement"), with Prolaio, Inc., pursuant to which we acquired 100% of the outstanding capital stock of Prolaio, Inc. Upon the consummation of the merger, Prolaio, Inc. became our wholly-owned subsidiary. Through the acquisition of Prolaio, Inc., we gained access to Prolaio, Inc.'s cardiovascular data collection and analytics platform. The total purchase consideration transferred was approximately $8.6 million, consisting of approximately $4.0 million in cash, primarily used to settle certain of Prolaio, Inc.'s outstanding debts, and fair value of contingent consideration of $4.6 million, representing the estimated acquisition date fair value of milestone payments. Pursuant to the Original Prolaio Merger Agreement, the former stockholders of Prolaio, Inc. were entitled to an aggregate of up to $200 million in milestone payments, which were payable as follows: (i) up to $50 million upon (A) our completion of a qualifying Phase 2 or Phase 3 clinical trial, (B) there being at least 500 Kardigan clinical trial patients managed and screened by Prolaio, (C) our achievement of annual gross revenues of $15 million from the sale of Prolaio products and services and (D) Prolaio achieving improvements in patient screening rates; (ii) up to $100 million upon (A) our completion of a qualifying Phase 2 or Phase 3 clinical trial, (B) there being at least 1,500 Kardigan clinical trial patients managed and screened by Prolaio, (C) our achievement of annual gross revenues of $25 million from the sale of Prolaio products and services and (D) Prolaio's achievement of improvements in patient screening rates; (iii) up to $200 million upon (A) our completion of a qualifying Phase 2 or Phase 3 clinical trial, (B) there being at least 5,000 Kardigan clinical trial patients managed and screened by Prolaio, (C) our achievement annual gross revenues of $25 million from the sale of Prolaio products and services and (D) Prolaio's achievement of improvements in patient screening rates; (iv) up to $200 million upon (A) our completion of a qualifying Phase 2 or Phase 3 clinical trial and (B) our achievement of annual net sales of $50 million from the sale of Prolaio products and services; and (v) 50% of Eligible Payments (as defined below) upon (A) our completion of a qualifying Phase 2 or Phase 3 clinical trial and (B) the execution of a commercial transaction for Prolaio products and services that results in payments to Kardigan, as calculated in accordance with terms of the Original Prolaio Merger Agreement ("Eligible Payments"); in each case excluding intercompany transactions, to the extent such milestones are achieved on or before February 28, 2029.

We concluded that Prolaio, Inc. constitutes a business and the transaction was accounted for as a business combination. In connection with the acquisition, we recorded $13.8 million of net assets acquired, primarily consisting of developed technology with a fair value of $25.4 million, acquired IPR&D asset with a fair value of $1.1 million, and $13.8 million in liabilities assumed, including $4.5 million of deferred income tax liability and $3.3 million of assumed contingent consideration liability. Because the fair value of net identifiable assets acquired exceeded the fair value of the consideration transferred, we recognized a gain on bargain purchase in an amount of $5.2 million in the condensed consolidated statement of operations and comprehensive loss for the three months ended June 30, 2025 and for the year ended December 31, 2025. The bargain purchase gain reflects our ability to acquire Prolaio at a purchase price below the fair value of the acquired net assets due to a combination of factors, including Prolaio's limited operating scale, historical operating losses, liquidity constraints at the time of the transaction, and the structure of the consideration transferred. In particular, concurrent with the acquisition, we entered into integration bonus arrangements with our Chief Executive Officer and Chief Medical Officer

("Integration Bonus"), both of whom were cofounders and Prolaio shareholders. These arrangements were contingent upon post-combination services and successful integration and, accordingly, were accounted for as compensation expense rather than consideration transferred.

In May 2026, we entered into Amendment No. 1 to Agreement and Plan of Merger ("Amendment No. 1") with the former stockholders of Prolaio, Inc. in order to amend the milestone provisions applicable to such stockholders, including Mr. Gianakakos and Dr. Edelberg. In particular, the milestones were revised to: (i) better align the incentives of the former stockholders of Prolaio, Inc., in their capacities as executive officers and employees of Kardigan, with the creation of stockholder value for us and (ii) better reflect our current operations and strategic direction following the acquisition, including our focus on deploying the Prolaio platform in support of its own clinical trials, and to ensure that the milestones remained aligned with our business.

Pursuant to the Amended Prolaio Merger Agreement and subject to the conditions therein, the former stockholders of Prolaio, Inc., including Mr. Gianakakos and Dr. Edelberg, are entitled to milestone payments as follows: (i) up to $50 million upon our achievement of a valuation equal to or greater than $5.0 billion; (ii) up to $50 million upon our achievement of a valuation equal to or greater than $6.0 billion; and (iii) up to $100 million upon our achievement of a valuation equal to or greater than $12.0 billion; in each case to the extent such milestones are achieved on or before May 1, 2032. Such milestone payments shall be payable in cash or shares of our common stock, at our election.

Prior to the Prolaio amendment, changes in the fair value of the contingent consideration were recognized in R&D expenses in the condensed consolidated statements of operations and comprehensive loss. Subsequent to the Prolaio amendment, changes in the fair value of the contingent milestone liabilities are recognized in change in fair value of contingent milestone liabilities, in the condensed consolidated statements of operations and comprehensive loss. The fair value of the Prolaio Contingent Consideration was $3.8 million as of December 31, 2025. Upon the Prolaio amendment, on May 1, 2026, the Prolaio Contingent Consideration was settled and the new contingent milestone liabilities were recognized at an initial fair value of $13.7 million. The fair value of the contingent milestone liabilities was $47.3 million as of June 30, 2026. We recognized a $43.5 million increase in the fair value of contingent milestone liabilities, which is presented within change in fair value of contingent milestone liabilities in the condensed consolidated statements of operations, for both the three and six months ended June 30, 2026. No change in fair value was recorded in the three and six months ended June 30, 2025. None of the Prolaio milestones, original or amended, had been achieved by June 30, 2026, and no milestone payments have been made.

Acquisition of RSF

On March 11, 2024, we entered into an Agreement and Plan of Merger with RSF (the "RSF Merger Agreement"), pursuant to which, on June 6, 2024, we acquired 100% of outstanding capital stock of RSF. RSF holds a patent license and know-how agreement with Mayo, originally effective December 6, 2019, as amended, granting an exclusive license to Mayo's proprietary methods and materials for treating calcific aortic valve stenosis. RSF also holds four exclusive option agreements with Mayo covering additional small-molecule programs and indications. The acquisition included Ataciguat (HMR1766), in addition to RSF's other existing agreements such as supply and license agreements with Sanofi and its affiliates. The closing was conditioned upon our completion of a Series A redeemable convertible preferred stock financing with gross proceeds of at least $150.0 million, which condition was satisfied on June 6, 2024.

As initial consideration, the acquisition involved upfront cash payments totaling $3.5 million, the settlement of RSF's outstanding indebtedness of $10.6 million on June 6, 2024, and the payment of certain transaction costs of $0.7 million incurred by RSF. We accounted for the transaction as the acquisition of a VIE that is not a business. The net assets acquired consisted primarily of the IPR&D asset, cash and cash equivalents in an amount of $0.2 million, and assumed accounts payable for an amount of $1.3 million. Accordingly, the consideration allocated to the IPR&D asset amounted to $15.9 million. The acquired licensed technology was determined to be an IPR&D asset that did not have alternative future use as of the acquisition date, and the full amount was recognized as research and development expense in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2024.

In addition to the initial consideration, and subject to the conditions set forth in the RSF Merger Agreement, the former stockholders of RSF are entitled to milestone payments of up to $26.5 million in development and regulatory milestones, and up to $249.5 million in sales milestones, in each case to be allocated among such former stockholders on a pro rata basis in accordance with their respective ownership interests in RSF immediately prior to the acquisition. We are additionally obligated to pay to the former stockholders of RSF low-single digit tiered royalties on annual net sales of any pharmaceutical product containing Ataciguat. The royalty term ends on a product-by-product and country-by-country basis on the earliest of (i) our cessation of development or commercialization of the applicable product, (ii) the expiration of the last-to-expire valid

patent claim covering the product in such country, or (iii) the first commercial sale of a generic product in the same indication in such country.

During the year ended December 31, 2025, we achieved the first development milestone associated with Ataciguat upon dosing of the first patient in the Phase 3 clinical trial. This milestone triggered a payment obligation of $3.0 million. As a result, we recognized $3.0 million in research and development expenses for the year ended December 31, 2025 in our consolidated statement of operations and comprehensive loss. Of the total milestone amount, $1.5 million was settled in cash and the remaining $1.5 million was accrued for in our consolidated balance sheet as of December 31, 2025 and as of June 30, 2026 within accrued and other current liabilities. None of the other RSF milestones had been achieved nor were deemed probable and estimable as of June 30, 2026, and no other milestone payments have been made.

License and collaboration agreements

Below is a summary of the key terms for certain of our license and collaboration agreements. For a more detailed description of these agreements, see Note 5 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

License agreements with BMS Co.

In November 2024, we entered into a License Agreement with MyoKardia, a wholly owned subsidiary of BMS Co., related to Danicamtiv and other compounds (the "Dani Agreement"), and a separate License Agreement with BMS Co. related to KAR-141 (formerly known as BMS-986141) ("Par4") and other compounds (the "Par4 Agreement").

Dani agreement

Under the Dani Agreement, we received an exclusive, sublicensable (subject to certain conditions and restrictions), royalty-bearing license under certain MyoKardia patents and know-how to develop, manufacture, and commercialize Danicamtiv (formerly known as MYK-491) and certain related compounds thereto (the "Dani Lead Compounds"), certain back-up compounds and certain related compounds thereto (such compounds, collectively with the Dani Lead Compounds, the "Dani Licensed Compounds"), and pharmaceutical products containing the Dani Licensed Lead Compounds (the "Dani Lead Compound Licensed Products") and pharmaceutical products containing the Dani Back-Up Compounds (such products, collectively with the Dani Lead Compound Licensed Products, the "Dani Licensed Products") for all human uses worldwide. As partial consideration for the rights granted to us under the Dani Agreement, we entered into a Subscription Agreement with MyoKardia pursuant to which we issued 1,251,107 shares of Series A redeemable convertible preferred stock to MyoKardia. As additional consideration for the licenses granted under the Dani Agreement, we are required to pay MyoKardia: (i) tiered royalties at a rate based on aggregate annual net sales by us, our affiliates and sublicensees of each Dani Licensed Product containing the same Dani Licensed Compound; (ii) a low double-digit percentage of any sublicensing revenue received by us, if we sublicense rights under MyoKardia patents or know-how for the development, manufacture or commercialization of any Dani Lead Compound or Dani Lead Compound Licensed Product to a third party within a certain number of months from the effective date, or November 2026; (iii) up to $42.5 million in the aggregate in development and regulatory milestone payments across all Dani Licensed Products and (iv) up to $265.0 million in sales milestone payments for each of the first two Dani Licensed Products to achieve the applicable sales milestones. Our tiered royalties range from a subteen to high teen percentage of annual net sales of the Dani Licensed Products, subject to potential reductions following the expiration of valid patent claims, due to competition from generic products, for certain third party license fees, and in the event of a limit on the maximum price as a result of the Inflation Reduction Act of 2022 (the "Inflation Reduction Act"), subject to a customary reduction floor and potential carry-forward.

Par4 agreement

Under the Par4 Agreement, we received an exclusive, sublicensable (subject to certain conditions and restrictions), royalty-bearing license under certain BMS Co. patents and know-how to develop, manufacture, and commercialize Par4 and certain related compounds thereto (the "Par4 Lead Compounds"), certain back-up compounds and certain related compounds thereto (such compounds, collectively with the Par4 Lead Compounds, the "Par4 Licensed Compounds"), pharmaceutical products containing the Par4 Lead Compounds (the "Par4 Lead Compound Licensed Products") and pharmaceutical products containing the Par4 Back-Up Compounds (such products, collectively with the Par4 Lead Compound Licensed Products, the "Par4 Licensed Products") for all human uses worldwide. As partial consideration for the rights granted under the Par4 Agreement, we entered into a Subscription Agreement with BMS Co. pursuant to which we issued 293,469 shares of Series A redeemable convertible preferred stock. As additional consideration for the licenses granted under the Par4

Agreement, we are required to pay BMS Co.: (i) tiered royalties at a rate based on aggregate annual net sales by us, our affiliates and sublicensees of each Par4 Licensed Product containing the same Par4 Licensed Compound; (ii) a low double-digit percentage of any sublicensing revenue received by us, if we sublicense rights under BMS Co. patents or know-how for the development, manufacture or commercialization of any Par4 Lead Compound or Par4 Lead Compound Licensed Product to a third party within a certain number of months from the effective date, or November 2026; (iii) up to $10.0 million in the aggregate in development and regulatory milestone payments across all Par4 Licensed Products and (iv) up to $265.0 million in sales milestone payments for each of the first two Par4 Licensed Products to achieve the applicable sales milestones. Our tiered royalties range from a subteen to high teen percentage of annual net sales of the Par4 Licensed Products, subject to potential reductions following the expiration of valid patent claims, due to competition from generic products, for certain third party license fees, and in the event of a limit on the maximum price as a result of the Inflation Reduction Act, subject to a customary reduction floor and potential carry-forward. Additionally, certain BMS Co. patents and know-how are sublicensed by BMS Co. pursuant to an upstream license agreement with a university and we are responsible for reimbursing BMS Co. for certain milestone payments and other amounts payable under such upstream agreement that arise from our development, manufacturing or commercialization activities under the Par4 Agreement. The milestone reimbursement obligations include up to (i) $12.5 million in the aggregate in development and regulatory milestone payments per certain Par4 Licensed Products and (ii) $13.625 million in the aggregate in development and regulatory milestone payments per certain other Par4 Licensed Products.

In connection with the Dani and Par4 license agreements, we issued an aggregate of 1,544,576 shares of Series A redeemable convertible preferred stock to MyoKardia and BMS Co., including 1,251,107 shares of Series A redeemable convertible preferred stock under the Dani Agreement, and 293,469 shares of Series A redeemable convertible preferred stock under Par4 Agreement, at the estimated fair value of $19.10 per share as of issuance date, with a total estimated fair value of $29.5 million. We determined that the Dani and Par4 licenses represent acquired IPR&D assets that did not have alternative future use as of the acquisition date, and, accordingly, an amount of $29.5 million was recognized as research and development expense in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2024. As of June 30, 2026, none of the Dani milestones or Par4 milestones had been achieved nor were deemed probable or estimable, and no milestone payments have been made.

License agreement with Ionis

On June 7, 2024, we entered into a License Agreement (the "Ionis License Agreement") with Ionis, pursuant to which we were granted an exclusive, worldwide, sublicensable (subject to certain conditions and restrictions), royalty-bearing license under certain Ionis intellectual property to develop and commercialize Tonlamarsen (formerly ION904) and products containing Tonlamarsen (the "Licensed Ionis Products") in the field of prophylactic or therapeutic use in humans (the "Ionis Licensed Field"). We also received a non-exclusive, worldwide, sublicensable (subject to certain conditions and restrictions), royalty-bearing license under certain Ionis intellectual property to manufacture Tonlamarsen and Licensed Ionis Products in the Ionis Licensed Field. Until the third anniversary of the effective date of the Ionis License Agreement, or June 2027, neither party may develop or commercialize, or assist or grant a third party rights to develop or commercialize certain ASOs designed to bind to the RNA encoded by the human angiotensinogen gene, subject to certain conditions and exceptions. As initial consideration for the Ionis License Agreement, we made an upfront payment of $20.0 million to Ionis. We determined that the licenses represent an acquired IPR&D asset that did not have alternative future use as of the acquisition date, and, accordingly, the total amount of the upfront payment of $20.0 million was recognized as research and development expense in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2024.

As additional consideration for the licenses and rights granted to us by Ionis, we are required to pay Ionis: (i) milestone payments in the event of successful achievement of specified development and sales milestones of up to an aggregate of $375.0 million (up to $35.0 million in development and regulatory milestone payments and up to $340.0 million in sales milestone payments); (ii) tiered royalties on net sales of Ionis Licensed Products by us, our affiliates and sublicensees with a rate based on net sales per calendar year, ranging from a subteen percentage to high teen percentage. The royalties are subject to potential reductions under certain scenarios. In the event that we undergo a change of control prior to receiving regulatory approval by the FDA and are acquired by one of certain top biopharmaceutical or pharmaceutical companies, if the acquisition price exceeds a certain dollar value, we will be required to pay Ionis a one-time change of control payment based on the acquisition price, ranging in the low tens of millions of dollars. The payment will accrue interest at a subteen percentage per annum, compounded annually, from the date of the Ionis License Agreement through the date such payment is made. As of June 30, 2026, none of the Ionis milestones had been achieved nor were deemed probable and estimable, and no milestone payments have been made.

License agreement with Sanofi

On June 2, 2021, RSF entered into a license agreement with Sanofi, as subsequently amended on March 18, 2022, January 9, 2023, and November 7, 2025 (collectively, the "Sanofi License"), under which RSF received a worldwide, exclusive, sublicensable (subject to certain conditions and restrictions), royalty-bearing license under certain Sanofi know-how to exploit Ataciguat (also known as HMR1766) and pharmaceutical products containing Ataciguat ("Ataciguat Products") for all human and mammalian therapeutic, prophylactic and diagnostic uses (the "Sanofi License Field"). RSF became our wholly owned subsidiary in June 2024. If we succeed in developing and commercializing Ataciguat Products, we will be obligated to pay Sanofi up to an aggregate of $14.8 million in potential commercial milestone payments. As of June 30, 2026, none of the Sanofi milestones had been achieved nor were deemed probable and estimable, and no milestone payments have been made. We are also obligated to pay Sanofi tiered royalties ranging from low-single digit to mid-single digit percentages on worldwide annual net sales of Ataciguat Products by us or our affiliates and sublicensees.

Patent license and know-how agreement with Mayo

On December 6, 2019, RSF entered into a license agreement with Mayo, as amended on May 20, 2021, August 23, 2023, March 10, 2024, June 6, 2024, and December 22, 2025 (collectively, the "Mayo License"), under which RSF received (i) a worldwide exclusive license with the right to sublicense (through multiple tiers) under certain Mayo patent rights, (ii) a nonexclusive license with the right to sublicense (through multiple tiers) to use certain know-how and materials, and (iii) a nonexclusive worldwide license, with the right to sublicense (through multiple tiers) in connection with a sublicense of the Mayo patent rights or know-how, subject to approval from Mayo, to use certain Mayo data, in each case in (i) through (iii), to develop, make, have made, use, offer for sale, sell, and import certain licensed products, including Ataciguat, for the prevention, diagnosis, and/or treatment of any and all human diseases and conditions. We are also obligated to pay Mayo up to $0.3 million in development and regulatory milestone payments and up to $1.3 million in commercial milestone payments for each licensed product to achieve the corresponding milestone events. As of June 30, 2026, none of the Mayo milestones had been achieved nor were deemed probable and estimable, and no milestone payments have been made.

We are also obligated to pay Mayo royalties ranging from a mid-single digit to subteen percentage of worldwide annual net sales by us, our affiliates and sublicensees of licensed products. In the event that we are required to pay a non-affiliate third party certain consideration for a license under intellectual property rights owned or controlled by such non-affiliate third party that are required for the manufacture, use or sale of the licensed products, we can deduct a certain amount of such consideration from the royalty payments due to Mayo under the Mayo Agreement, subject to a customary reduction floor.

Critical accounting policies and estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which are prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of our condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements and accompanying notes. We base our estimates and assumptions on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and judgments on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

See Note 2, *"Summary of Significant Accounting Policies"* to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, for information about our significant accounting policies and estimates used in the preparation of our condensed consolidated financial statements. There have been no significant and material changes in our critical accounting policies during the three and six months ended June 30, 2026, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the year ended December 31, 2025 included in the final prospectus dated June 17, 2026 filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

Emerging growth company and smaller reporting company status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards and

as a result of this election, our consolidated financial statements may not be comparable to companies that comply with public company effective dates. We may take advantage of these exemptions up until the time that we are no longer an "emerging growth company."

We will remain an emerging growth company until the earlier of the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means, among other things, the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, or (d) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this Quarterly Report on Form 10-Q and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than what you might receive from other public reporting companies in which you hold equity interests. In addition, the JOBS Act provides that an "emerging growth company" can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we can adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an "emerging growth company."

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until for so long as either (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenues are less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Recent accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2, "*Summary of Significant Accounting Policies*" to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Off-balance sheet arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of June 30, 2026, the end of the period covered by this Quarterly Report on Form 10-Q. Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2026 at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

Due to a transition period established by SEC rules applicable to newly public companies, our management is not required to evaluate the effectiveness of our internal control over financial reporting until the filing of our Annual Report on Form 10-K for the year ended December 31, 2027. As a result, this Quarterly Report on Form 10-Q does not address whether there have been any changes in our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources, negative publicity and reputational harm.

Item 1A. Risk Factors.

Our business involves significant risks. Stockholders should carefully consider the risks and uncertainties described below, together with all of the other information included in this Quarterly Report on Form 10-Q, and in the other documents that we file with the SEC. Our business, financial condition, results of operations and prospects could be materially and adversely affected if any of these risks occur, and as a result, the market price of our common stock could decline, and stockholders could lose part or all of their investment.

This Quarterly Report also contains forward-looking statements that involve risks and uncertainties not presently known to us or that we currently deem to be immaterial. See "Cautionary Note Regarding Forward-Looking Statements" on page 1 for more information. Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain important factors, including those set forth below.

Risks related to our limited operating history, financial condition and need for additional capital

We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future success and viability. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in August 2023 as EnCarda, Inc., and our operations to date have been limited to organizing and staffing our company, business planning, including our acquisitions, raising capital, identifying, licensing and developing potential product candidates, acquiring, deploying and developing our Prolaio platform and technology, securing intellectual property rights, and planning and undertaking preclinical studies and clinical trials. Our lead product candidates include Danicamtiv for genetic dilated cardiomyopathy ("DCM"), Ataciguat for moderate calcific aortic valve stenosis ("CAVS") and Tonlamarsen for post-hospitalization management of acute severe hypertension ("ASH").

We have not yet demonstrated an ability to generate revenues, obtain regulatory approvals, manufacture any product on a commercial scale or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Our limited operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage 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 suffer.

The success of our business depends primarily upon our ability to identify, develop, and commercialize our product candidates, Danicamtiv, Ataciguat and Tonlamarsen and develop our Prolaio platform. We do not know whether we will be able to develop any product candidates that succeed through preclinical and clinical development or products of commercial value. We have no products approved for commercial sale and have not generated any revenue from product sales to date. We will continue to incur significant research and development and other expenses related to our preclinical and clinical development and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net losses totaled $172.3 million and $75.5 million for the six months ended June 30, 2026 and 2025, respectively, and $191.9 million and $88.7 million for the year ended December 31, 2025 and 2024, respectively. As of June 30, 2026, we had not yet generated revenues and had an accumulated deficit of $453.4 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- advance our product candidates through clinical development, including as we continue to advance Danicamtiv, Ataciguat and Tonlamarsen in later-stage clinical trials;
- continue to develop our Prolaio platform;
- seek regulatory approvals from the U.S. Food and Drug Administration (the "FDA") or other foreign regulatory authorities for our product candidates that successfully complete clinical trials;

- hire additional clinical, quality control, medical, scientific and other technical personnel to support the clinical development of our product candidates;
- experience an increase in headcount as we expand our research and development organization and market development and pre-commercial planning activities;
- undertake any pre-commercial or commercial activities to establish sales, marketing and distribution capabilities;
- advance our existing and potential future preclinical-stage product candidates into clinical development;
- seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates, which may include opportunities to leverage our Prolaio platform;
- maintain, expand and protect our intellectual property portfolio;
- experience heightened regulatory scrutiny;
- make milestone, royalty or other payments due under our existing license agreements with MyoKardia, Inc. ("MyoKardia"), Bristol-Myers Squibb Company ("BMS Co."), Sanofi, the Mayo Foundation for Medical Education and Research ("Mayo") and Ionis Pharmaceuticals, Inc. ("Ionis") and our purchase agreements with Rancho Santa Fe Bio, Inc. ("RSF") and Prolaio, Inc., and any future in-license or collaboration agreements;
- make milestone, royalty, interest or other payments due under any future licensing, financing or other arrangements with third parties; and
- incur additional legal, accounting, and other expenses associated with operating as a public company.

Biopharmaceutical product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ours, should be carefully considered. Any predictions about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

Additionally, our expenses could increase beyond our expectations if we are required by the FDA, European Medicines Agency (the "EMA"), or other comparable regulatory authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of any of our product candidates.

We will require substantial additional capital to finance our operations in the future. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or 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. We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek regulatory and marketing approval for, our product candidates. Even if our current or future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. To date, we have funded our operations through private financings and our recent initial public offering. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the clinical and preclinical development of our product candidates, continue to identify new product candidates, develop and deploy our Prolaio platform, commence additional preclinical studies and clinical trials, and continue to identify and develop additional product candidates either through internal development or through acquisitions or in-licensing product candidates.

As of June 30, 2026, we had $660.7 million of cash, cash equivalents and investments. We believe that our existing cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the date of issuance of the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. Based on our current operating plan, we expect our current cash runway to support the

continued advancement of Danicamtiv, Ataciguat and Tonlamarsen through clinical data readouts and the initiation of Phase 3 clinical trials across all three programs. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We may also raise additional financing on an opportunistic basis in the future. For example, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. Our future capital requirements will depend on many factors, including but not limited to:

- the scope, timing, progress, costs and results of discovery, preclinical development and clinical trials for our current or future product candidates;
- the number of clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing and outcome of regulatory review of any of our current or future product candidates;
- the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses, as applicable;
- the cost of manufacturing clinical and commercial supplies of our current or future product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to deploy and develop the Prolaio platform, including in connection with our current and future product candidates;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of macroeconomic trends, including inflation, tariffs and fluctuating interest rates;
- any potential supply chain interruptions or delays;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in additional businesses, products and technologies.

Because of the numerous risks and uncertainties associated with research and development of product candidates, we are unable to predict the timing or amount of our working capital requirements. In addition, if we obtain regulatory approval for our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution which make it difficult to predict when or if we will be able to achieve or maintain profitability. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to support our continuing operations. Our ability to raise additional funds will depend on financial, economic, political and market conditions and other factors, over which we may have no or limited control. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. 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, future commercialization efforts or other operations.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations with our existing cash, cash equivalents and short-term investments, any future equity, debt or other financings and upfront and milestone and royalty payments, if any, received under any future licenses or collaborations. If we raise additional capital through the sale of equity or convertible debt securities, or issue any equity or convertible debt securities in connection with a collaboration agreement or other contractual arrangement, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. In addition, the possibility of such issuance may cause the market price of our common stock to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring, selling or licensing intellectual property rights or assets, which could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, operating results and prospects.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions and changes in financial regulations and policies can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. In addition, changes in regulations governing financial institutions are beyond our control and difficult to predict; consequently, the impact of such changes on our business and results of operations is difficult to predict and may have an adverse effect on us.

Risks related to our business

Our business is highly dependent on the success of our product candidates, particularly Danicamtiv for genetic DCM, Ataciguat for moderate CAVS, and Tonlamarsen for post-hospitalization management of ASH. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.

To date, as an organization, we have not completed the development of any product candidates. Our future success and ability to generate revenue from our product candidates is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates. All of our product candidates will require substantial additional investment for clinical development, regulatory review and approval in one or more jurisdictions. If any of our product candidates, particularly Danicamtiv for genetic DCM, Ataciguat for moderate CAVS and Tonlamarsen for ASH, encounters safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of our product candidates if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- our inability to demonstrate to the satisfaction of the FDA, EMA, or other comparable regulatory authorities that our product candidates are safe and effective;
- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- future product-related adverse events (“AEs”) experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates;

- delays in submitting an Investigational New Drug ("IND") application or other regulatory submission to the FDA, EMA, or other comparable regulatory authorities, or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA, EMA, or other comparable regulatory authorities regarding the scope or design of our clinical trials;
- poor effectiveness of our product candidates during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- delays in enrolling subjects in our clinical trials;
- high drop-out rates of subjects from our clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- higher than anticipated clinical trial or manufacturing costs;
- unfavorable FDA, EMA or comparable regulatory authority inspection and review of our clinical trial sites;
- failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;
- competition with existing platforms, product candidates or therapies;
- delays and changes in regulatory requirements, policies and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular;
- insufficiency of our financial and other resources to complete the necessary activities to prepare for launch commercialization and/or resources to address coverage and reimbursement matters to the extent any of our product candidates receive approval; or
- varying interpretations of data by the FDA, EMA, or other comparable regulatory authorities.

The successful development of pharmaceutical products involves a lengthy and expensive process and is highly uncertain.

Successful development of pharmaceutical products involves a lengthy and expensive process, is highly uncertain, and is dependent on numerous factors, many of which are beyond our control. Failure can occur at any time during the preclinical study or clinical trial process. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and the historical failure rate for product candidates in our industry is high. The results from preclinical studies or early clinical trials of a product candidate may not predict the results of later clinical trials of the product candidate, and interim results of a clinical trial are not necessarily indicative of final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- clinical trial results may show the product candidates to be less effective than expected (for example, a clinical trial could fail to meet its primary or key secondary endpoint(s)) or have an unacceptable safety or tolerability profile;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which, among other things, may be caused by patients who fail the trial screening process, slow enrollment in clinical trials, patients dropping out of trials, patients lost to follow-up, length of time to achieve trial endpoints, additional time requirements for data analysis or New Drug Application ("NDA") or similar foreign application preparation, discussions with the FDA, EMA, or other comparable regulatory authority, an FDA, EMA, or other comparable regulatory request for additional preclinical or clinical data (such as long-term toxicology studies) or unexpected safety or manufacturing issues;
- preclinical study results may show the product candidate to be less effective than desired or to have harmful side effects;

- post-marketing approval requirements; or
- the proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized.

Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations in the United States or country-specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced. Even if we are able to obtain coverage and adequate reimbursement for our products once approved, there may be features or characteristics of our products, such as dose preparation requirements, that prevent our products from achieving market acceptance by the healthcare or patient communities.

In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current Good Manufacturing Practices ("cGMPs") and Good Clinical Practices ("GCPs") for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post-approval, such as AEs of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-approval could adversely affect our business, financial condition and results of operations.

Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.

Our lead product candidates, Danicamtiv for treatment of genetic DCM, Ataciguat for treatment of moderate CAVS, and Tonlamarsen for post-hospitalization management of ASH, are at various stages of clinical development. Danicamtiv is being evaluated in the ongoing KINSHIP-DCM Phase 2b/3 trial, Ataciguat is being evaluated in an ongoing KATALYST-AV Phase 2b trial and Tonlamarsen is being evaluated in the ongoing KARDINAL-ASH Phase 2 trial. We seek to rapidly advance discovery and development of transformational medicines for patients suffering from cardiovascular diseases.

Due to the significant resources required for the development of our product candidates, 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, therapeutic areas or indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, in particular for cardiovascular diseases, our business, financial condition and results of operations could be materially and adversely affected. 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 and disease pathways 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 royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties or other strategic alliances. The failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing clinicians' and patients' needs, competitive technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may

enhance our capabilities, complement our existing products and technologies or expand the breadth of our markets or customer base. For example, in February 2025, we acquired 100% of the equity interests in Prolaio, Inc., a clinical intelligence company developing patient data collection software, and in June 2024, we acquired RSF, a clinical-stage cardiovascular platform company. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products, employees or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management's attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers, sales agents, health care facilities, surgeons and other health care providers;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms, if at all, or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers, sales agent, health care facilities, physicians or other health care providers. Our ability to successfully grow through strategic transactions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses, technologies or products and to obtain any necessary financing. These efforts could be expensive and time-consuming and may disrupt our ongoing business and prevent management from focusing on our operations. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits. Furthermore, we may experience losses related to investments in other companies, including as a result of failure to realize expected benefits or the materialization of unexpected liabilities or risks, which could have a material negative effect on our results of operations and financial condition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, financial condition, results of operations and prospects.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our common stock as consideration. Additional funds may not be available on terms that are favorable to us, or at all.

We may experience challenges with the acquisition, development, enhancement or deployment of technology necessary for our Prolaio platform.

The Prolaio platform requires sophisticated computer systems and software for data collection, data processing, cloud-based platforms, analytics, and other applications and technologies. We are building artificial intelligence ("AI") technologies into internal applications and solutions and we expect our use of AI to increase.

Some of these technologies are changing rapidly and we must continue to adapt to these changes in a timely and effective manner at an acceptable cost. There can be no guarantee that we will be able to develop, acquire or integrate new technologies, that these new technologies will meet our needs or those of our clients' or achieve expected investment goals, or that we will be able to do so as quickly or cost-effectively as our competitors. Our continued success will depend on our ability to adapt to changing technologies, manage and process ever-increasing amounts of data and information and improve the performance, features and reliability of our services. We may experience difficulties that could delay or prevent the successful design, development, testing, introduction or marketing of our services. New services, or enhancements to existing services, may not adequately meet our own requirements or those of current and prospective clients or achieve any degree of

significant market acceptance. Regulations relating to the use of AI and the interpretation of those regulations by regulators, courts and others are in the early stages of development and evolving, which may make it difficult to identify adequate compliance requirements or suitable governance practices to meet those requirements. These types of failures could have a material adverse effect on our operating results, financial condition and reputation.

We have entered into, and may in the future enter into, related party transactions that may have terms that are less favorable to us.

We have in the past been and may in the future be party to certain transactions with certain entities affiliated with our directors, executive officers and principal stockholders. For example, we acquired Prolaio, Inc. in February 2025 pursuant to an Agreement and Plan of Merger (the "Original Prolaio Merger Agreement"), as amended by Amendment No. 1 (as defined below) (together, the "Amended Prolaio Merger Agreement"). Pursuant to the Original Prolaio Merger Agreement, the former stockholders of Prolaio, Inc. were entitled to an aggregate of up to $200 million in milestone payments, which were payable as follows: (i) up to $50 million upon (A) our completion of a qualifying Phase 2 or Phase 3 clinical trial, (B) there being at least 500 Kardigan clinical trial patients managed and screened by Prolaio, (C) our achievement of annual gross revenues of $15 million from the sale of Prolaio products and services and (D) Prolaio achieving improvements in patient screening rates; (ii) up to $100 million upon (A) our completion of a qualifying Phase 2 or Phase 3 clinical trial, (B) there being at least 1,500 Kardigan clinical trial patients managed and screened by Prolaio, (C) our achievement of annual gross revenues of $25 million from the sale of Prolaio products and services and (D) Prolaio's achievement of improvements in patient screening rates; (iii) up to $200 million upon (A) our completion of a qualifying Phase 2 or Phase 3 clinical trial, (B) there being at least 5,000 Kardigan clinical trial patients managed and screened by Prolaio, (C) our achievement of annual gross revenues of $25 million from the sale of Prolaio products and services and (D) Prolaio's achievement of improvements in patient screening rates; (iv) up to $200 million upon (A) our completion of a qualifying Phase 2 or Phase 3 clinical trial and (B) our achievement of annual net sales of $50 million from the sale of Prolaio products and services; and (v) 50% of Eligible Payments (as defined below) upon (A) our completion of a qualifying Phase 2 or Phase 3 clinical trial and (B) the execution of a commercial transaction for Prolaio products and services that results in payments to Kardigan, as calculated in accordance with terms of the Original Prolaio Merger Agreement ("Eligible Payments"); in each case excluding intercompany transactions, to the extent such milestones are achieved on or before February 28, 2029. At the time of the acquisition, Tassos Gianakakos, our Chief Executive Officer, also served as the Chief Executive Officer and a member of the board of directors of Prolaio, Inc. and Jay Edelberg, our Chief Medical Officer, served as Head of Research and Development and a member of the board of directors of Prolaio, Inc. Mr. Gianakakos and Dr. Edelberg beneficially owned 55.7% and 17.1%, respectively, of Prolaio, Inc. at the time of its acquisition by us. If such milestone payments became payable, subject to the maximum aggregate limit of $200 million, Mr. Gianakakos would have been entitled to receive payments of up to $106.6 million in the aggregate, and Dr. Edelberg would have been entitled to receive payments of up to $32.9 million in the aggregate.

In May 2026, we entered into Amendment No. 1 to Agreement and Plan of Merger ("Amendment No. 1") with the former stockholders of Prolaio, Inc. in order to amend the milestone provisions applicable to such stockholders, including Mr. Gianakakos and Dr. Edelberg. In particular, the milestones were revised to: (i) better align the incentives of the former stockholders of Prolaio, Inc., in their capacities as executive officers and employees of Kardigan, with the creation of stockholder value for Kardigan; and (ii) better reflect our current operations and strategic direction following the acquisition, including our focus on deploying the Prolaio platform in support of our own clinical trials, and to ensure that the milestones remained aligned with our business.

Pursuant to the Amended Prolaio Merger Agreement and subject to the conditions therein, the former stockholders of Prolaio, Inc., including Mr. Gianakakos and Dr. Edelberg, are entitled to an aggregate of up to $200 million in milestone payments as follows: (i) up to $50 million upon Kardigan's achievement of a valuation equal to or greater than $5.0 billion; (ii) up to $50 million upon Kardigan's achievement of a valuation equal to or greater than $6.0 billion; and (iii) up to $100 million upon Kardigan's achievement of a valuation equal to or greater than $12.0 billion; in each case to the extent such milestones are achieved on or before May 1, 2032. If such milestone payments become payable, Mr. Gianakakos is entitled to receive payments of up to $12.9 million, $31.3 million and $62.4 million, respectively, pursuant to each milestone, for a total of up to $106.6 million; and Dr. Edelberg is entitled to receive payments of up to $3.6 million, $9.8 million, and $19.5 million, respectively, pursuant to each milestone, for a total of up to $32.9 million.

Although we believe that these transactions are in our best interests, we cannot assure you that these transactions were entered into on terms as favorable to us as those that could have been obtained in an arm's-length transaction with unaffiliated third-parties. Conversely, we may not be able to enter into transactions with third parties on terms as favorable as the terms of existing or any future transactions with related parties. Further, the appearance of conflicts of interest created by

related party transactions could impair the confidence of our investors. It is possible that a conflict of interest could have a material adverse effect on our business, results of operations, and financial condition.

In connection with the initial public offering, we adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of related-person transactions.

We, third-parties on which we rely and our service providers are, or may become, subject to a variety of stringent and evolving data privacy and security laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Any actual or perceived failure to comply with such obligations could expose us to significant fines or other penalties and otherwise harm our business and operations.

In the ordinary course of our business, we and the third parties upon which we rely (such as our third party Contract Research Organizations ("CROs") and other contractors and consultants) collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "process") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third-party data, business plans, transactions, financial information and data we collect about trial participants in connection with clinical trials (collectively, sensitive data). Through our acquisition of Prolaio, Inc., we have acquired an FDA-cleared patient data collection software platform and cardiovascular clinical data, which we use to enhance data collection and analysis in our clinical trials. Prolaio's operations significantly expand the volume and sensitivity of patient health data we process, including high-density patient data collected through Prolaio's data collection software and clinical datasets. Our data processing activities subject us to numerous evolving data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. The legislative and regulatory framework for the processing of personal data worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer, use and share sensitive data, 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 regulations, our internal policies and procedures or our contracts governing our processing of sensitive data could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operations, and financial condition.

In the United States, numerous federal, state and local laws and regulations, including federal health information privacy laws, state information security and data breach notification laws, federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws) govern the processing of health-related and other personal data. At a federal level, HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission of and breach reporting related to individually protected identifiable health information ("PHI"). We may obtain health information from third parties, such as research institutions with which we collaborate, that are subject to privacy and security requirements under HIPAA. Although we do not believe that we are directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we knowingly obtain or disclose PHI maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA. We currently use the Prolaio platform for our own clinical research purposes. To the extent we obtain PHI from covered entities under HIPAA, such as hospitals or clinical trial sites, for use with the Prolaio platform or otherwise, we may be required to enter into data use agreements or business associate agreements and comply with applicable contractual and regulatory requirements for the use and disclosure of such information, including requirements related to de-identification, limited data sets, appropriate administrative, physical and technical safeguards, and breach notification. If we were to expand Prolaio, Inc.'s operations to provide services to external healthcare providers or other covered entities, we could become subject to more extensive HIPAA business associate obligations, including direct enforcement by the U.S. Department of Health and Human Services Office for Civil Rights, which could impose civil monetary penalties as well as criminal penalties for violations of HIPAA.

We may also obtain patient health records through platforms that participate in the Trusted Exchange Framework and Common Agreement ("TEFCA"), a nationwide health information exchange framework established under the 21st Century Cures Act and administered by ONC. TEFCA imposes privacy, security, and individual rights requirements, including individual consent and data deletion rights, on entities that participate in TEFCA exchange activities. We obtain patient records through a third-party platform operating as an Individual Access Services provider under TEFCA, pursuant to which individuals consent to retrieval of their health records for use in our clinical research. Depending on the scope of our participation in TEFCA exchange activities, we may be subject to TEFCA's contractual obligations, including obligations

that may conflict with data retention requirements under the Common Rule and FDA clinical trial regulations. The application of TEFCA's requirements to clinical research is an area of evolving legal interpretation for which regulatory guidance remains limited. Failure to comply with applicable TEFCA requirements, or changes in how those requirements are interpreted or enforced, could require us to modify our data collection practices in ways that adversely affect our clinical operations or expose us to contractual liability or regulatory scrutiny.

At the state level, numerous U.S. states have enacted comprehensive privacy laws, such as the California Consumer Privacy Act (the "CCPA") and several others that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording individuals certain rights concerning their personal data. Similar laws and several others in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these comprehensive privacy laws that are in effect at the state level generally exempt certain data processed in the context of clinical trials, the continued development of new privacy laws at the state level may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Further proposed privacy legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of data and information that could be of potential use to the growth and development of our business and could result in increased compliance costs and/or the necessity of making changes in our business practices and policies. The continued further development of privacy laws in different states could make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance that could adversely impact our financial condition. Additionally, we may be subject to laws governing the privacy of specific types of data, including, biometric information and, notably, consumer health data. For example, Washington's My Health My Data Act broadly defines consumer health data, creates a private right of action to allow individuals to sue for violations of the law, imposes stringent consent requirements and grants consumers certain rights with respect to their health data, including to request deletion of their information. Connecticut and Nevada have also passed similar laws regulating consumer health data. These various data privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. Such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by these U.S. state privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's General Data Protection Regulation and Data Protection Act 2018 (collectively, the "UK GDPR" and together with the EU GDPR, the "GDPR") impose strict requirements for processing personal data of individuals within the European Economic Area ("EEA") and the United Kingdom ("UK"). These European regimes include strict requirements relating to processing of sensitive data (such as health data), ensuring there is a legal basis or condition to justify the processing of personal data, obtaining consent of individuals in certain circumstances, disclosing how personal data is to be used, limiting retention of information, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, maintaining records of processing activities, documenting data protection impact assessments where there is high-risk processing and taking certain measures when engaging third-party processors.

Under GDPR, companies may face temporary or definitive bans on data processing and other corrective activities, fines of up to €20 million (£17.5 million GBP) or 4% of the annual global revenues of the noncompliant undertaking, whichever is greater, private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests; or regulatory investigations, reputational damage, orders to cease/change our data processing activities, enforcement notices and/or assessment notices (for a compulsory audit). Non-compliance could also result in a material adverse effect on our business, financial position and results of operations.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries or we may have to implement additional measures to enable such transfers due to data localization requirements or limitations on cross-border data flows. Among other requirements, the GDPR restricts the 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, unless a derogation exists or we implement a valid GDPR transfer mechanism (for example, the European Commission approved Standard Contractual Clauses and the UK International Data Transfer Agreement/Addendum and conduct transfer impact assessments to assess whether the recipient can ensure certain guarantees under the GDPR). However, the efficacy and longevity of current transfer mechanisms remains uncertain. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by

regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, 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.

The UK's data protection regime is independent from but aligned to the EU's data protection regime. However following the UK's departure from the European Union ("Brexit"), there will be increasing scope for divergence in application, interpretation and enforcement of the data protection laws between these territories. For example, the UK Data (Use and Access) Act 2025 (the "UK Act"), now in force, further alters the similarities between the UK and EEA data protection regimes. In December 2025, the European Commission adopted a decision determining that the UK continues to provide a level of data protection that is "essentially equivalent" to the EU standards and extended the validity of the UK adequacy decision for six years, through December 2031. While this renewal reduces immediate adequacy concerns for transfers of personal data from the EEA to the UK, uncertainty remains regarding how UK data protection laws will evolve in the medium to longer term. This lack of clarity on future UK laws and regulations and their interaction with those of the EU could add legal risk, uncertainty, complexity, and cost to our handling of European personal data and our privacy and security compliance programs, and any resulting divergence in laws could increase our risk profile and may require us to implement different compliance measures for the UK and EEA. In addition, EEA Member States have adopted national laws to implement the GDPR that may partially deviate from the GDPR. Further, the competent authorities in the EEA Member States interpret GDPR obligations slightly differently from country to country (particularly in relation to the processing of health data) and therefore we do not expect to operate in a uniform legal landscape in the EEA. The European Commission has also proposed further reforms under the so-called "Digital Omnibus" package, which is intended to streamline and update aspects of the EU's digital regulatory framework, including certain data protection obligations. While the scope and final form of these proposals remain subject to legislative negotiation, if adopted they may further modify or supplement existing GDPR-related requirements, including by further clarifying the scope of what constitutes "personal data" and the regulatory treatment of coded, key-coded or otherwise de-identified data. Any such changes could require us to reassess and adjust our European privacy compliance framework, resulting in additional legal, operational and compliance costs.

Additionally, in 2025, the U.S. Department of Justice issued a rule entitled Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restrictions on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and generally prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to these countries of concern. The rule impacts certain business or management activities such as vendor engagements, licensing arrangements, partnership engagements, sale or sharing of data, employment of certain individuals and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. We may in the future engage in data transactions that could be subject to the rule. There is a risk that our interpretation of the rule's applicability, scope and requirements could be incorrect, incomplete, or misapplied. The rule applies to certain data transactions even where data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which may impact our ability to enter into certain agreements.

In addition to data privacy and security laws, we are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We may publish privacy policies and marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. Regulators such as the U.S. Federal Trade Commission are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail (or be perceived to have failed) to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the

volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; potentially significant penalties if we are found to be in violation of our privacy obligations; adverse publicity; or substantial changes to our business model or operations.

Our information technology systems and infrastructure, or those of our collaborators and service providers, or our data, may be subject to cyber-attacks, intrusions, breaches, compromises, disruptions or other cybersecurity incidents, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand, material disruption of our development programs and operations, or other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely, process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats that could cause cyber-attacks, intrusions, breaches, compromises, disruptions or other cybersecurity incidents. Although we take steps to develop and maintain systems and controls designed to protect our sensitive data, systems and infrastructure, there can be no assurance that our internal technology systems and infrastructure, or those of third parties upon which we rely, will be sufficient to protect against a cyber-attack, intrusion, breach, compromise, disruption or other cybersecurity incident such as an industrial espionage attack, ransomware, or insider threat attack such as wrongful conduct by employees or vendors, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our sensitive data. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

The risk of a cyber-attack, intrusion, breach, compromise, disruption or other cybersecurity incident has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have grown. Such risks come from a variety of evolving threats, including but not limited to, social engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), misconfigurations, "bugs" or other vulnerabilities in software that is integrated into our technology systems and infrastructure, malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats. Further, there can also be no assurance that our and our third-party service providers', strategic partners', contractors', consultants', CROs' and collaborators' 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 sensitive data.

Threat actors engage in and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely, may be vulnerable to a heightened risk of cyber-attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services. Additionally, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

We also face increased risks of a cyber-attack, intrusion, breach, compromise, disruption or other cybersecurity incident due to our reliance on internet technology and the number of our employees who work on a hybrid basis at home, in the office, or other public spaces. This may create additional opportunities for cybercriminals to exploit vulnerabilities. Additionally, business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies that were not found during due diligence of such acquired or integrated entities.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts and our ability to monitor these third parties' information security practices is limited. These third parties may not have adequate information security measures in place and if our third-party service

providers experience a cyber-attack, security breach, compromise, disruption or other cybersecurity incident, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or cybersecurity-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

We may be unable to detect vulnerabilities in our information technology systems and infrastructure on a timely basis or until after a cyber-attack, intrusion, breach, compromise, disruption or other cybersecurity incident has occurred, and it may be difficult and/or costly to investigate, mitigate, contain, and remediate a cybersecurity incident. Further, we may experience delays in developing and deploying remedial measures designed to adequately address any such identified vulnerabilities. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a cybersecurity incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

We have in the past experienced threats related to our data and systems, and we may in the future experience additional threats, compromises, breaches or other cybersecurity incidents. If we, or a third party upon whom we rely, experience a cyber-attack, intrusion, breach, compromise, disruption or other cybersecurity incident, or are perceived to have experienced one, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including individual and group claims); significant incident response, system restoration or remediation costs; indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other potentially significant harms. Further, applicable data privacy and cybersecurity obligations may require us to notify individuals, regulators, or other relevant stakeholders of a cyber-attack, intrusion, breach, compromise, disruption, or other cybersecurity incident. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. In addition, cyber-attacks, intrusions, breaches, compromises, disruptions or other cybersecurity incidents may cause stakeholders (including investors and potential customers) to stop supporting our business, deter new customers from using our products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and cybersecurity obligations. Further, our existing general liability and cyber liability insurance policies may not cover, or may cover only a portion of, any potential claims related to cybersecurity breaches to which we are exposed or may not be adequate to indemnify us for all or any portion of liabilities that may be imposed. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a cybersecurity incident or breach or that the insurer will not deny coverage of any future claim. Accordingly, if our cybersecurity measures, and those of our service providers, fail to protect against unauthorized access, attacks (which may include sophisticated cyberattacks) and the mishandling of data by our employees and third-party service providers, then our reputation, business, results of operations and financial condition could be adversely affected.

The use of new and evolving technologies, such as AI and machine learning ("ML"), in our operations, and the operations of third parties upon which we rely, may result in spending additional resources and present new risks and challenges that can impact our business including by posing cybersecurity and other risks to our sensitive data, and as a result we may be exposed to reputational harm, other adverse consequences, and liability.

We use and integrate AI/ML systems in our business, primarily in our Prolaio platform. The use of new and evolving technologies, such as AI/ML, in our operations, and the operations of third parties upon which we rely, presents new risks and challenges that could negatively impact our business, including cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational, and other risks and challenges. Specifically, risks related to bias, AI hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks such as model poisoning or data poisoning, surveillance, data leakage, loss of consensus reality, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies.

We expect that increased investment will be required in the future to continuously improve our AI/ML systems. As with many technological innovations, there are significant risks involved in developing, maintaining and deploying these technologies and there can be no assurance that the usage of our investments in such technologies will always enhance our products or services or be beneficial to our business, including our efficiency or profitability.

The use of certain AI/ML technology can give rise to intellectual property risks, including by disclosing or otherwise compromising our confidential or proprietary intellectual property and intellectual property infringement, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of AI/ML tools. For example, we may experience difficulties in enforcing the intellectual property rights in output generated by AI/ML technologies. The United States Copyright Office has previously denied copyright protection for content generated by AI/ML technologies, and the United States Patent and Trademark Office has similarly stated that an AI/ML tool cannot be an "inventor" of a patent, rendering it impossible to obtain patent protection for inventions created solely by AI/ML technologies. The Supreme Court of the United Kingdom has reached a similar conclusion, stating that AI/ML systems cannot be named as an "inventor" for UK patent law purposes. Additionally, several jurisdictions around the globe, including in Europe and the U.S., have proposed, enacted, or are considering, laws governing the development and use of AI/ML, such as the EU's AI Act. As amended by the Digital Omnibus package, which received final Council approval in June 2026, the obligations applicable to providers and deployers of high-risk AI systems under the EU AI Act have been deferred and are now scheduled to apply from December 2, 2027. If we use AI/ML systems that are governed by the EU AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. We expect other jurisdictions will adopt similar laws.

In the U.S., the regulatory framework for AI/ML technologies faces significant uncertainty. At the federal level, Congress has yet to enact meaningful AI legislation. In the absence of federal AI legislation, states have filled the void by enacting laws regulating different aspects of AI/ML technologies. For example, California has enacted laws and regulations related to AI/ML safety protocols, reporting and transparency, among other AI-related topics. In addition, Colorado's Automated Decision-Making Technology Act will impose various disclosure and transparency requirements on developers and deployers of various AI/ML systems. Numerous other states have enacted, passed, or are considering AI-focused legislation, creating a patchwork of regulations and a complex compliance challenge. The current administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. Any failure or perceived failure by us to comply with existing or newly enacted laws, regulations and other requirements relating to AI/ML technologies could result in legal claims or proceedings (including class actions), regulatory investigations or enforcement actions.

Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, lead to regulatory fines or penalties, require us to change our business practices, retrain our AI/ML, or prevent or limit our use of AI/ML. For example, the Federal Trade Commission has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated certain privacy and consumer protection laws. If we cannot use AI/ML or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

The rapid evolution of AI/ML will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that AI/ML is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate AI/ML tools into their own offerings, and the providers of these AI/ML tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to data privacy and cybersecurity. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI/ML, to expand potential attack surfaces and otherwise engage in illegal activities involving the theft and misuse of sensitive data. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Risks related to the discovery and development of our current or future product candidates

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

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities, such as the EMA and national competent authorities in EU Member States, impose similar requirements. The time required to obtain approval by the FDA, EMA, or other comparable regulatory authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. For instance, jurisdictions outside of the United States, such as the European Union or Japan, may have different requirements for regulatory approval, which may require us to conduct additional clinical, nonclinical or chemistry, manufacturing and control studies. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any product candidate. We must complete additional preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Before obtaining approval from regulatory authorities for the commercialization of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our initial and potential additional product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of AEs that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA, EMA, or other comparable regulatory authorities that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates have a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well-tolerated when that is not in fact the case. Serious AEs or other AEs, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA, or other comparable regulatory authorities may disagree as to the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA, or other comparable regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA, or other comparable regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA, or other comparable regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA, EMA, or other comparable regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA, or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, financial condition, results of operations and prospects. The FDA, EMA, and other comparable regulatory authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA, or other comparable regulatory authorities. Furthermore, the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, 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 materially harm the commercial prospects for our product candidates.

In addition, FDA and foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. In April 2024, the European Parliament adopted its position on the legislative proposals and, in June 2025, the Council of the European Union adopted its position. A common position on the text was agreed upon on December 11, 2025, in the context of subsequent inter-institutional trilogue negotiations. The proposed revisions remain to be adopted into EU law, and are not expected to become applicable before 2028. The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term.

The FDA, EMA or comparable regulatory authorities may disagree with our regulatory plan for our product candidates.

The general approach for FDA approval of a new drug is dispositive data from two or more adequate and well-controlled clinical trials of the product candidate in the relevant patient population. Adequate and well-controlled clinical trials typically involve a large number of patients, have significant costs and take years to complete. The FDA, EMA or other comparable regulatory authorities may disagree with us about whether a clinical trial is adequate and well-controlled or may request that we conduct additional clinical trials prior to regulatory approval. In addition, there is no assurance that the doses, endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. For instance, we may seek FDA regulatory flexibility and pursue marketing approval based on data from only one adequate and well-controlled clinical investigation. However, the FDA may not agree with our proposed development plans, and our clinical trial results may not support approval of our product candidates for our target indications. In addition, our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the FDA, EMA, or comparable regulatory authorities may not file or accept our NDA or marketing application for substantive review;
- the FDA, EMA, or comparable regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials;
- the FDA, EMA, or comparable regulatory authorities may determine there is not substantial evidence of effectiveness to support approval;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA, or comparable regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA, EMA, or comparable regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA, EMA, or comparable regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA, EMA, or comparable regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA, EMA, or comparable regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA, or comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical studies and clinical trials that were previously conducted for our product candidates.

All of our lead product candidates were initially developed by third parties. For example, Danicamtiv was initially developed by MyoKardia and further developed by BMS Co., Ataciguat was initially developed by Sanofi and Mayo and Tonlamarsen was developed by Ionis. We in-licensed each of these product candidates pursuant to license agreements with BMS Co., Sanofi and Mayo, and Ionis, respectively. We entered into these licenses on the basis of our interpretation of the medical and scientific meaningfulness of each product candidate's initial data. Therefore, we are dependent on third-parties such as MyoKardia, BMS Co., Sanofi, Mayo and Ionis having designed certain preclinical studies and clinical trials and conducted their research and development in accordance with the applicable protocols, legal and regulatory requirements, and scientific standards; having accurately reported the results of all preclinical studies conducted with respect to such product candidates; and having correctly collected and interpreted the data from these studies and trials. These risks also apply to any additional product candidates that we may acquire or in-license in the future. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of our product candidates will be adversely affected and the earlier-reported results may not support data that we generate in our own preclinical or clinical work with those product candidates.

Our use of the Prolaio platform to enhance clinical trial design and execution is a novel approach that may not result in the anticipated efficiencies or regulatory acceptance, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development.

A key element of our strategy is utilizing our Prolaio platform, which leverages AI-enabled tools to optimize the development of our product candidates in clinical development, including by enhancing the design and execution of our clinical trials through improved patient identification and enrollment, and continuous real world data collection. While we believe the Prolaio platform has the potential to expand patient access and accelerate patient recruitment and trial execution for our own trials and when sold to third-parties for use in third-party clinical trials, the Prolaio platform is a novel approach to trial design and execution. As a result, we are exposed to a number of unforeseen risks related to our Prolaio platform, and these risks could impact each of our product candidates. For example, digital clinical endpoints collected through our Prolaio platform may not be accepted by the FDA as valid primary or secondary endpoints, which could require additional validation work, modification of trial design or the collection of additional clinical endpoint data, potentially delaying development timelines. The regulatory framework for digital health technologies and digitally-obtained endpoints continues to evolve. Because it is a novel approach, to date, we have not used Prolaio to support regulatory decision-making, and the use of Prolaio in our clinical trials to support regulatory decision-making for our therapeutic candidates has not yet been validated by the FDA. While our clinical studies of Danicamtiv and Ataciguat are exploring the use of Prolaio to capture eVO2peak (our novel estimate of pVO_2, which is a clinically accepted measure of a patient's functional capacity derived from Cardiopulmonary Exercise Testing ("CPET"), our primary endpoint evaluates pVO_2 to support regulatory decision-making and we do not intend to seek approval on the basis of the eVO2peak measurements collected by Prolaio. In the future, we will need to validate Prolaio biomarkers with the FDA to be used as endpoints for a given disease. Even if validated by the FDA, we may not realize Prolaio's potential to support smaller, faster, and more capital efficient clinical trials, and it may not meet our expectations in speeding the development of our programs and increasing the probability of success.

Although our research and development efforts to date have resulted in a development portfolio of programs and product candidates, we may not be able to discover or identify additional candidates or clinical research that could appropriately utilize our Prolaio platform. Even if we are successful in continuing to build and expand our development portfolio, the potential product candidates that we identify may not be successful in clinical development. If we do not successfully deploy the Prolaio platform to develop and commercialize additional product candidates, we may not realize the anticipated benefits of developing and utilizing our Prolaio platform, which likely would result in significant harm to our financial position and adversely affect our stock price.

If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.

The results observed from preclinical studies or early-stage clinical trials of our product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. For instance, results seen in our Phase 2 trial of Danicamtiv for DCM may not translate to similar results in our ongoing KINSHIP-DCM Phase 2b/3 clinical trial. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as other product candidates that we believe may have similar profiles.

In addition, in our ongoing and planned future clinical trials, we may utilize clinical trial designs or dosing regimens that have not been routinely tested in prior clinical trials similar to ours. For instance, in our KATALYST-AV trial for Ataciguat, we are exploring novel endpoints, including change in valve area calcium and peak VO_2, in patients with aortic stenosis. In our KINSHIP-DCM study for Danicamtiv, we are deploying an adaptive trial design where the effects observed in the Phase 2b portion of the study may impact the statistical analysis and sample size of the Phase 3 portion of the study. In our KARDINAL-ASH study for Tonlamarsen, we plan to leverage Prolaio data collection during the post-discharge period to characterize blood pressure control, blood pressure excursions and cardiovascular parameters.

There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse effects or AEs.

Additionally, we may utilize an "open-label" clinical trial design for certain of our clinical trials. For example, our Phase 2 trial for Danicamtiv was an open-label clinical trial. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. A common concern with open-label clinical trials is an increased susceptibility to bias, including "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results of a product candidate when studied in a controlled environment with a placebo or active control. Accordingly, data from our Phase 2 trial for Danicamtiv may not be predictive of data from our planned clinical trials for Danicamtiv.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval.

We intend to conduct certain clinical trials for our product candidates outside of the U.S. However, the FDA and comparable foreign regulatory authorities may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We may conduct certain clinical trials for our product candidates outside of the U.S. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of this data is subject to certain conditions imposed by the FDA or may not be accepted at all. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U.S., the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for regulatory approval unless the study is well-designed and well-conducted in accordance with

GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted.

For studies that are conducted only at sites outside of the U.S. and not subject to an IND, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which could require us to conduct additional clinical trials. Conducting clinical trials outside the U.S. also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. We currently have clinical trial sites for Danicamtiv, Ataciguat, and Tonlamarsen outside the United States and may in the future conduct further clinical trials with one or more trial sites that are located outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA, and there can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an IND or similar foreign authorization, or not approving or delaying approval for any clinical trial grant or similar approval we need to initiate a clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, institutional review boards ("IRBs") or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which may be required to resubmit to an IRB and regulatory authorities for re-examination;

- regulators or other reviewing bodies may find deficiencies with, fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the potential for approval policies or regulations of the FDA, EMA, or other comparable regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval.

Clinical trials must be conducted in accordance with the FDA, EMA, and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. Regulators or IRBs of the institutions in which clinical trials are being conducted may suspend, limit or terminate a clinical trial, or data monitoring committees may recommend that we 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, EMA, or other comparable regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications.

We do not know whether any clinical trials that we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates for the indications that we are pursuing. If later-stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates will be adversely impacted.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries. Additionally, recent policy proposals in the U.S., if enacted in the future, may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly.

Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would significantly harm our business. Our product candidate development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. There can be no assurance that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. In addition, many of the factors that cause, or lead to, the termination, suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates may be associated with AEs or other undesirable properties or safety risks, which could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials or abandon a product candidate, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained, or result in other significant negative consequences that could severely harm our business, financial condition, results of operations, and prospects.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and, if such product candidates are approved, could result in a more restrictive label, the inclusion of a risk evaluation and mitigation strategy ("REMS"), or the delay or denial of regulatory approval by the FDA, EMA, or other comparable regulatory authorities. Any treatment-related side effects could also affect patient recruitment or

the ability of enrolled patients to complete the trial, or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly.

We may observe safety or tolerability issues beyond those we anticipate with our current or future product candidates in ongoing or future clinical trials. Additionally, it is possible that human subjects with cardiovascular diseases may experience greater side effects in our clinical programs than observed in healthy volunteers. We continue to learn more about our product candidates, and unfavorable pharmacology profiles, including extended half-lives, could lead to adverse outcomes or concerns by the FDA, EMA, or other comparable regulatory authorities.

Many compounds that initially showed promise in clinical or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Results of future clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing.

At any time, we may decide to terminate or greatly narrow the target population for a clinical development program due to unacceptable side effects or safety concerns.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, EMA, or other comparable regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA, EMA, or other comparable regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. We may be unable to overcome any such suspensions or holds that are placed on our clinical trials. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may materially adversely affect our business, financial condition, results of operations and prospects.

Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone. Other potentially significant negative consequences associated with AEs include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or change their approvals of a product;
- regulatory authorities may require additional warnings on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies;
- we may be required to change the way a product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and

- a product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

Our product candidates have been associated with treatment-related serious adverse events in clinical trials, and such events may delay or prevent regulatory approval, cause us to suspend or discontinue clinical trials, or otherwise harm our business.

We have not yet completed any pivotal clinical trials with our product candidates. While the data reported to date from the ongoing clinical evaluation of our product candidates indicate that they have been generally well tolerated, there remains a risk of treatment-related serious adverse events ("TRSAEs") for all of our product candidates. As of August 6, 2026, TRSAEs have been observed in clinical trials conducted with our product candidates, as described below. It is possible that additional or increased occurrences or severity of TRSAEs and serious adverse events will occur in human subjects during ongoing and planned clinical trials, and the severity and rate of these events may not be acceptable in patients with cardiovascular diseases.

- Danicamtiv. In clinical trials conducted with Danicamtiv, two participants had a total of three TRSAEs as assessed by the investigator. One participant had complete atrioventricular ("AV") block (mild, recovered) and one participant had two TRSAEs: liver injury (severe, resolved) and acute kidney injury (moderate, recovered). After a careful review of these two SAEs, other confounding factors, such as comorbidities, drug allergy, nitrofurantoin use, and hypotension, were identified as possible causes of liver injury and acute kidney injury. Based on this review, the Sponsor at the time (BMS Co.) considered these two SAEs to be not related to Danicamtiv.
- Ataciguat. In clinical trials conducted with Ataciguat, nine TRSAEs have been reported, each occurring in one participant except for two hepatic events occurring in two participants (increased hepatic enzymes, drug-induced liver injury). Eight TRSAEs were recovered and/or resolving, with one TRSAE (hematuria) whose outcome was unknown. Three TRSAEs were categorized severe and included one report each of atrial fibrillation, increased serum creatine phosphokinase, and cerebrovascular disorder. Two TRSAEs were categorized as moderate severity, and included one report each of drug-induced liver injury and hypersensitivity. A single TRSAE was categorized as mild, which was reported as chronic kidney disease. The three remaining TRSAEs (dizziness, hematuria, and increased hepatic enzymes) were of unknown severity.
- Tonlamarsen. In clinical trials conducted with Tonlamarsen, three SAEs were reported as related to the study medication by the investigator, each occurring in one participant. The reported TRSAEs were increased blood glucose, which was categorized as serious, loss of consciousness, which was categorized as moderate severity, and one TRSAE of fatal renal failure. Both the increased blood glucose TRSAE and loss of consciousness were recovered and resolved. The SAE of fatal renal failure occurred many weeks after the end of study visit. After careful review the sponsor considered this SAE to be unrelated to Tonlamarsen due to the prolonged time lapse from last dose of study medication and onset of symptoms.

Undesirable side effects caused by any of our product candidates could cause us, the data safety monitoring boards for such trials, IRBs or ethics committees of the institutions in which such trials are being conducted, or regulatory authorities to interrupt, delay, suspend, halt or place on clinical hold the associated clinical trials and could result in a more restrictive label, the imposition of distribution or use restrictions, requirements to conduct additional studies, dose de-escalation, or additional protocol amendments, or the delay or denial of regulatory approval by the FDA, EMA, or other comparable regulatory authorities. Treatment-related side effects could also affect site initiation, patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Even if serious adverse events are unrelated to study treatment, such occurrences could affect patient enrollment or the ability of enrolled patients to complete the clinical trial. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, and we may not be able to complete a clinical trial for any of our product candidates on the timeline we expect, or at all.

Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered when a significantly larger number of patients have been exposed to the drug candidate, including post-approval, and there can be no assurance that our product candidates will not cause more severe and/or serious side effects in a greater proportion of patients.

If unexpected adverse events occur in any of our clinical trials, we may need to abandon development of our product candidates, or limit development to lower doses or to certain uses or subpopulations in which the undesirable side effects or other unfavorable characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, and we may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and, upon any commercialization of our product candidates, if approved. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any such findings could cause delays in completion or cancellation of our clinical programs, and may harm our business, financial condition, results of operations, and prospects significantly.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates.

Any product candidate we develop and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States, and by the EMA and other comparable regulatory authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval.

Our team expects to rely on third-party CROs or regulatory consultants to assist us in submitting and supporting the applications necessary to gain marketing approvals. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude its obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA, EMA, and other comparable 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. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

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

From time to time, we may publish interim, topline or preliminary data from our clinical trials and preclinical studies. Such announcements or publications are typically 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 interim, topline, or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from

the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

Interim data from clinical trials that we may complete are further 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 interim, topline or preliminary data and final data could significantly harm our reputation and business prospects. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock.

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 is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities, or otherwise regarding a particular product candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations, and prospects.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the development and commercialization of our product candidates may be delayed, and our business, financial condition and results of operations may be harmed.

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA, EMA, and other comparable regulatory authorities, if at all, and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used to manufacture our product candidates;
- the efforts of our collaborators with respect to the commercialization of our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business, financial condition and results of operations may be harmed.

We have concentrated our research and development efforts on the treatment of cardiovascular diseases, a field that faces certain challenges in drug development.

We have focused our research and development efforts on addressing cardiovascular diseases. Developing a product candidate for treatment of the cardiovascular diseases we currently target is extremely difficult and subjects us to a number of

unique challenges, including obtaining regulatory approval from the FDA and other regulatory authorities who have only a limited set of precedents to rely on. Efforts by pharmaceutical companies in this field have faced certain challenges in drug development. In particular, cardiovascular disease conditions present similarly but stem from diverse disease biology and genetic variability. In addition, traditional clinical trials in cardiovascular diseases have resulted in large, expensive trials. Further, background medications commonly prescribed for aortic stenosis patients, such as beta blockers, may impact pulmonary function measurements and can impact our results.

Moreover, given the history of clinical failures in this field, future clinical or regulatory failures by us or others may have resulted in further negative perception of the likelihood of success in this field, which may significantly and adversely affect the market price of our common stock. We intend to work closely with the FDA, EMA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation in an effort to obtain regulatory approval for our product candidates; however, the process of developing our product candidates may be more complex and time-consuming relative to other more well-known approaches to drug development. We cannot be certain that our approach will lead to the development of product candidates that effectively and safely address our target indications.

We may be subject to additional risks because we may in the future evaluate our product candidates in combination with the standard of care for the indications that we are pursuing.

We may in the future evaluate our product candidates in combination with other compounds, specifically the standard of care for the indications that we are pursuing. The use of our product candidates in combination with such other compounds may subject us to risks that we would not face if our product candidates were being administered as a monotherapy. The outcome and cost of developing a product candidate to be used with other compounds is difficult to predict and dependent on a number of factors that are outside our control. If we experience efficacy or safety issues in our clinical trials in which our product candidates are being administered with other compounds, we may not receive regulatory approval for our product candidates, which could prevent us from ever generating revenue or achieving profitability.

For example, the combination of our product candidates and the standard of care may result in unexpected adverse side effects or toxicities. In addition, the product candidates may interact with other companies' products or product candidates that the patients receiving our product candidates may also be receiving, in undesirable ways. Testing product candidates in patients already receiving other treatments may increase the risk of significant adverse effects or failed clinical trials. The timing, outcome and cost of the potential adverse effects of developing products to be used in patients already receiving other therapies is difficult to predict and dependent on a number of factors that are outside our reasonable control. If serious adverse or unexpected side effects are identified during development and are determined to be attributed to our product candidates, or the result of drug-drug interactions between our product candidate and any of the concomitant therapies given to the trial subjects, we, the FDA, EMA, comparable foreign regulatory authorities, or IRBs and other reviewing entities could interrupt, delay, or halt clinical trials. Such findings could also result in delays in, or denial of, regulatory approval by the FDA, the EMA, or comparable foreign regulatory authorities. Further, even if our product candidates are approved, these findings could result in a more restrictive label or particularly narrow indication (substantially limiting the product's commercial opportunities) or a REMS.

Moreover, any safety, efficacy, regulatory, manufacturing or supply issues that could arise with respect to an already approved therapy with which our product candidates are developed for use could have an adverse impact on us. Prescribing information for the approved therapy, such as risk information like a boxed warning, or limitations of use, could negatively impact our ability to commercialize a product as an add-on or as further supportive care to the approved therapy. If the approved therapy is replaced as the standard of care, the FDA, EMA or comparable foreign regulatory authorities may require us to conduct additional clinical trials, or we may not be able to obtain adequate reimbursement from third-party payors. The occurrence of any of these events could result in our product candidate, if successfully developed and approved, being removed from the market or being less successful commercially. If the FDA, EMA or comparable foreign regulatory authorities revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with respect to, therapies we choose to evaluate in conjunction with or as background or standard of care therapy for any of our product candidates, we may be unable to obtain regulatory approval of or to commercialize such product candidates in combination with these therapies. If we experience safety, tolerability or toxicity issues in any of our ongoing or planned clinical trials that allow patients to remain on other therapies, or if the efficacy or safety data from these trials of our candidates administered to patients on other therapies are not favorable, our clinical development plans could be materially negatively affected or delayed, or we may not receive regulatory approval for our product candidates, which would materially harm our business and likely cause the market price of our common stock to decline.

Even if our product candidate demonstrates clinical benefit as part of a combination regimen, payors may determine that the incremental value is insufficient to justify the overall cost and may refuse to reimburse at levels that are acceptable to us or that support commercial viability. In addition, we do not control the pricing, contracting strategy or reimbursement profile of any product for which we are developing our product candidates in companion, which may change over time and adversely impact the attractiveness or economics of the combination. If coverage for the companion therapy is reduced, withdrawn, or made more restrictive, the value proposition for our product candidate could be materially weakened.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with our protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion.

Patient enrollment is affected by many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the severity of the disease under investigation;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- patients that enroll in our clinical trials may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop such patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;
- approval of new indications for existing therapies or approval of new therapies in general;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in our clinical trials will drop out of the trials before completion.

We may experience challenges in recruiting principal investigators and patients to participate in ongoing and future clinical trials for such product candidates if we are unable to sufficiently demonstrate the potential of such product candidates to them. In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Our trials also include procedures, such as pulmonary function tests via CPET, that may be burdensome for patients and could hinder enrollment. In addition, we are pursuing novel or smaller indications, including ASH and genetic DCM, which may further affect our ability to enroll patients in our clinical studies. Furthermore, if significant AEs or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our trials and patients may drop out of our trials. Additionally, patients, including patients in any control groups, may withdraw from the clinical trial for various reasons, including but not limited to if they are not experiencing improvement in their underlying disease or condition, or if they experience other difficulties or issues relating to their underlying disease or condition. Withdrawal of patients from our clinical trials may compromise the quality of our data.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials or our development efforts altogether. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of our product candidates, cause our value to decline and limit our ability to obtain additional financing if needed.

The number of patients with certain cardiovascular diseases for which we are developing our product candidates has not been established with precision. If the actual number of patients with the diseases we elect to pursue with our product candidates is smaller than we anticipate, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. Even if such product candidates are successfully developed and approved, the markets for our product candidates may be smaller than we expect and our revenue potential and ability to achieve profitability may be materially adversely affected.

Our pipeline includes product candidates for a number of cardiovascular diseases. There is no precise method of establishing the actual number of patients with any of these diseases in any geography over any time period. With respect to many of the indications in which we have developed, are developing, or plan to develop our product candidates, we have estimates of the prevalence of the disease. Our estimates as to prevalence may not be accurate, and the actual prevalence or addressable patient population for some or all of those indications, or any other indication that we elect to pursue, may be significantly smaller than our estimates. In estimating the potential prevalence of indications we are pursuing, or may in the future pursue, including our estimates as to the prevalence of cardiovascular disease, we apply assumptions to available information that may not prove to be accurate. In each case, there is a range of estimates in the published literature and in marketing studies, which include estimates within the range that are lower than our estimates. The actual number of patients with these disease indications may, however, be significantly lower than we believe. Even if our prevalence estimates are correct, our product candidates may be developed for only a subset of patients with the relevant disease or our product candidates, if approved, may be indicated for or used by only a subset. In the event the number of patients with the cardiovascular diseases we are studying is significantly lower than we expect, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. If any of our product candidates are approved and our prevalence estimates with respect to any indication or our other market assumptions are not accurate, the markets for our product candidates for these indications may be smaller than we anticipate, which could limit our revenues and our ability to achieve profitability or to meet our expectations with respect to revenues or profits.

Even if any of our product candidates receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

We have never commercialized a product, and even if any of our product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to achieve sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. The commercial success of any of our product candidates will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications.

Even if our product candidates are successful in registrational clinical trials, they may not be successful in achieving market acceptance by physicians, patients, or third-party payors for addition to current standards of care if we are unable to demonstrate superior efficacy, safety, ease of administration and/or cost-effectiveness when prescribing our product candidates in addition to current standard of care treatments as add-on therapies. For example, physicians may be reluctant to add to their patients' current medications and adjust their treatment regimen for a variety of reasons. Further, patients often acclimate to the treatment regimen that they are currently taking and do not want to add-on additional treatments unless their physicians recommend doing so or are required to do so due to inadequate coverage or reimbursement by third-party payors. Even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, we may be unable to demonstrate to physicians, patients, or third-party payors the benefits of adding-on our product candidates or safety or efficacy concerns regarding our product candidates in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates as add-on therapies may require significant resources, including management time and financial resources, and may not be successful. If any product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product, including as compared to any more-established products or other alternative products that may later be approved;
- the potential advantages of the product compared to standard of care alone or competitive therapies;
- the indications for which the product is approved, if any;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;

- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with the product in the absence of sufficient third-party coverage and adequate reimbursement;
- the product's acceptance into standard of care treatment algorithms by medical societies as add-on treatments that could limit payor and physician uptake;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product;
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors, including any price concessions required by third-party payors to obtain coverage;
- potential product liability claims; and
- unfavorable publicity relating to the product, or favorable publicity about competitive products.

Any failure by one or more of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

If we fail to discover, develop and commercialize additional product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although the development and commercialization of our current product candidates are our initial focus, as part of our longer-term growth strategy, we plan to develop other product candidates. In addition to the product candidates in our clinical-stage pipeline, we have additional assets that are in earlier stages of development, such as KAR-141, which is licensed from BMS Co. We intend to evaluate internal opportunities from our existing product candidates or other potential product candidates, and also may choose to in-license or acquire other product candidates to treat patients suffering from other disorders with significant unmet medical needs and limited treatment options. These other potential product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA, EMA, or other comparable regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot be certain that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

In addition, we intend to devote substantial capital and resources for basic research to discover and identify additional product candidates. These research programs require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

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

In the future, we may also seek to in-license or acquire product candidates or the underlying technology. The process of proposing, negotiating and implementing a license or acquisition is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

If we are unsuccessful in identifying and developing additional product candidates, either through internal development or licensing or acquisition from third parties, our potential for growth and achieving our strategic objectives may be impaired.

Competitive products may reduce or eliminate the commercial opportunity for our product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.

The clinical and commercial landscapes for the treatment of cardiovascular diseases are highly competitive and subject to rapid and significant scientific and technological change. We face competition with respect to our indications for our product candidates and will face competition with respect to any other drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that are pursuing the development of drug candidates for the treatment of the indications that we are pursuing. 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.

We are aware that a significant number of product candidates are currently under development for the same indications that we are currently pursuing and may pursue, and some or all may become commercially available in the future for the treatment of conditions for which we are trying or may try to develop product candidates.

We do not currently plan to run head-to-head clinical trials evaluating our product candidates against the current standards of care, which may make it more challenging for our product candidates to compete against the current standards of care due to the lack of head-to-head clinical trial data.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our therapies obsolete or non-competitive before we can recover development and commercialization expenses. If any of our product candidates are approved, it could compete with a range of therapeutic treatments that are in development. In addition,

our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than our product candidates, which could render our product candidates obsolete and noncompetitive.

If we obtain approval for any of our product candidates, we may face competition based on many different factors, including the efficacy, safety and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

In addition, our competitors may obtain patent protection, regulatory exclusivities or FDA approval and commercialize products more rapidly than we do, which may impact future approvals or sales of any of our product candidates that receive regulatory approval. If the FDA approves the commercial sale of any product candidate, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receive regulatory approval but cannot compete effectively in the marketplace.

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 and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.

We currently have no marketing, sales or distribution capabilities for our product candidates. We intend to establish a sales and marketing organization, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize one or more of our product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates.

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel, at an acceptable cost, or at all;
- the inability of sales personnel to obtain access to or our failure to educate an adequate number of physicians on the benefits of any future products;
- 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 sales and marketing organization.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas. If we do

not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Risks related to employee matters and managing growth

We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs and sales, marketing and distribution, as well as to continue to support our public company operations. To manage these growth activities, we must continue to implement and improve our managerial, operational, quality and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. As we grow, including through the potential establishment of operations in additional geographic locations, we may face increased complexity in our organizational structure and greater challenges in maintaining effective oversight, communication and alignment across functions and locations. Our management may need to devote a significant amount of its attention to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

Our ability to develop product candidates and leverage our Prolaio platform and our future growth depends on attracting, hiring and retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management and scientific personnel, many of whom have been instrumental for us and have substantial experience with developing therapies, identifying potential product candidates and building the technologies related to the clinical development of our product candidates. Given the specialized nature of cardiovascular diseases and our approach, there is an inherent scarcity of experienced personnel in these fields. As we continue developing our product candidates in our pipeline and advance our Prolaio platform, we will require personnel with medical, scientific, or technical qualifications specific to each program. The loss of key personnel, in particular our Chief Executive Officer, Co-Founder and Chair of the Board, Chief Medical Officer, clinical development personnel and key employees at Prolaio, would delay our research and development activities. We currently do not have “key person” insurance on any of our employees. Despite our efforts to retain valuable employees, members of our team may terminate their employment with us on short notice. The competition for qualified personnel in the biotechnology, biopharmaceutical and digital health industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which would have a material adverse effect on our business.

In addition, our clinical operations and research and development programs depend on our ability to attract and retain highly skilled scientists, data scientists, and engineers, particularly in New Jersey, California, and Illinois. There is powerful competition for skilled personnel in these geographical markets, and we have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. The need to attract and retain talent across both traditional biopharmaceutical functions and digital health and technology functions increases the complexity of our recruiting and retention efforts. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

Risks related to our dependence on third parties

We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

We have relied upon and plan to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, clinical investigators and vendors to conduct our clinical trials and expect to rely on these third parties to conduct clinical trials of any other product candidates that we develop. Our ability to complete clinical trials in a timely fashion depends on a number of key factors. These factors include contract negotiation, protocol design, regulatory and IRB approval, site activation, budget negotiation, patient enrollment rates and compliance with GCPs. We have opened clinical trial sites and are enrolling patients in a number of countries where our experience is limited. In most cases, we use the services of third parties, including CROs, to carry out our clinical trial-related activities and rely on such parties to accurately report their results. Our reliance on third parties for clinical development activities may impact or limit our control over the timing, conduct, expense and quality of our clinical trials. If we are unable to successfully contract with or have to terminate and establish alternative service provider or site contractual relationships with any parties involved in or supporting our product candidate development activities, our clinical development could experience delays or be otherwise adversely impacted. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of clinical trial sponsors, principal investigators, clinical trial sites and IRBs. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States.

We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. Our failure or the failure of third parties to comply with the applicable protocol, legal and regulatory requirements and scientific standards can result in rejection of our clinical trial data or other sanctions. If we or our third-party clinical trial providers, vendors or third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or be unsuccessful. Additionally, if we or our third-party contractors fail to comply with applicable GCPs for any reason, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs. We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. Moreover, many CROs, including some of those that we have engaged to conduct our clinical trials, are experiencing enrollment challenges as a result of, among other things, high employee turnover driven by the post-COVID macroeconomic environment and the inexperience of new employees. Additionally, at clinical trial sites, the availability of staff and trial participants has been limited. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, 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 may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any logistical issues associated with the storage and distribution of our product candidates and other materials, such as errors or improper handling by distributors, transportation restrictions, or interruptions caused by natural disasters or force majeure events could delay clinical development or regulatory approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue. Certain of our product candidates may be sensitive to temperature, storage and handling conditions and the shipping, storage, handling and administration of our product

candidates may need to be performed according to specific instructions and in some steps within specific time periods. Failure to correctly handle our product candidates could negatively impact the efficacy and/or safety of our product candidates, or cause a loss of product candidates.

Any of the third-party organizations we utilize may terminate their engagements with us under certain circumstances. The replacement of an existing CRO or other third party may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, even if there are suitable replacements for one or more of these service providers, there is a natural transition period when a new service provider begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and/or a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

Our use of third parties to manufacture our product candidates, including those located outside of the United States in jurisdictions such as Europe, Canada and China, may increase the risk that we will not have sufficient quantities of our product candidates, raw materials, active pharmaceutical ingredients ("APIs") or drug products when needed or at an acceptable cost.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. Our current strategy is to outsource all manufacturing of our product candidates to third parties, including in jurisdictions outside of the United States such as Germany, Switzerland, Canada and China.

We currently rely on and engage third-party manufacturers to provide all of the API and the final drug product formulation of all of our product candidates that are being used in our clinical trials and preclinical studies. If we were to need an alternate manufacturer, we would incur added costs and delays in identifying and qualifying any such replacement. In addition, we typically order raw materials, API and drug product and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. We may not be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of our product candidates, and the costs of manufacturing could be prohibitive.

Many of the third-party manufacturers we rely on have only recently begun working with us and have limited or no experience manufacturing our API and final drug products. These third-party manufacturers are subject to cGMP compliance requirements of the FDA, EMA, and other comparable regulatory authorities where our product candidates may be shipped. If our manufacturers have difficulty or suffer delays in successfully manufacturing material that meets our specifications, it may limit supply of our product candidates, delay our initiation of clinical trial activities in jurisdictions where the requirements to supply clinical product have not been satisfactorily demonstrated, and could delay our clinical trials.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third-party manufacturer to comply with applicable regulatory requirements and reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;

- the failure of the third-party manufacturer to produce materials with acceptable quality on a larger scale;
- the possible breach of manufacturing agreements by third parties because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or fail to find them on favorable contractual terms, or fail to develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our product candidates. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA, EMA, and other comparable regulatory authorities.

Additionally, if any third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA, EMA, or other comparable regulatory authorities. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. The delays associated with the verification of a new third-party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidate that such third party owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such third-party manufacturer in order to have another third party manufacture our product candidates.

If any of our product candidates is approved by any regulatory agency, we intend to utilize arrangements with third-party contract manufacturers for the commercial production of those products. This process is difficult and time consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization.

Some of our manufacturers are located outside of the United States, including in China. There is currently significant uncertainty about the future relationship between the United States and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. Increased tariffs or pending legislation that would impose federal contracting or federal funding limitations on parties directly using or connected to those using the services or equipment of certain foreign entities with known or alleged associations with foreign adversaries could potentially disrupt our existing supply chains and impose additional costs on our business. Given the unpredictable regulatory environment in China and the United States and uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, litigation of tariffs in U.S. federal courts, additional taxes, contracting matters, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business and financial condition.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be evaluated by the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA, or other comparable regulatory authorities, we may not be able to secure and/or maintain regulatory approval for our product candidates manufactured at these facilities. 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 finds deficiencies

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. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

The FDA, EMA, or other comparable regulatory authorities require manufacturers to register manufacturing facilities, and also inspect these facilities to confirm compliance with cGMPs.

Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA, and other comparable regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval, if obtained.

Furthermore, should we decide to use any APIs in any of our product candidates that are proprietary to one or more third parties, we would need to maintain licenses to those APIs from those third parties. If we are unable to gain or continue to access rights to such APIs prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate APIs, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to gain or maintain continued access rights to the desired APIs on commercially reasonable terms or develop suitable alternate APIs, we may not be able to commercialize product candidates from these programs.

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

We may plan to opportunistically pursue strategic partnerships, as the advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. If we believe that partnerships can accelerate the development or maximize the market potential of our product candidates, we will consider entering into product, target and/or geographic specific strategic partnerships on an opportunistic basis. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain regulatory approval for product candidates from foreign regulatory authorities, we may enter into partnerships or collaborations with international biotechnology or pharmaceutical companies for the commercialization of such product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a partnership or collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed partnerships or collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA, EMA, or other comparable regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for partnership or collaboration and whether such a partnership or collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Partnerships and collaborations are each complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any partnership or collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential partnerships or collaborations or to otherwise develop specified product candidates. We may not be able to negotiate partnerships or collaborations on a timely basis, on acceptable terms, or

at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Furthermore, if conflicts arise between our collaborators and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Our collaborators could conduct multiple product development efforts and could develop, either alone or with others, products in related fields that are competitive with the product candidates we may develop that are the subject of these partnerships or collaborations with us.

Competing products may preclude us from entering into partnerships or collaborations with their competitors, fail to obtain timely regulatory approvals, prevent us from obtaining timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the partnership or collaboration efforts, including development, delivery, manufacturing and commercialization of products. Any of these developments could harm our company and product development efforts.

If we enter into collaborations with third parties for the development and commercialization of our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations.

We may enter into collaborations for the development and commercialization of certain of our product candidates. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, which divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, 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;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, including trade secrets and intellectual property rights, contract interpretation, or the preferred course of development might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- 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 potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- 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.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us.

If any third-party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates or increase the product yield of its manufacturing, then our manufacturing costs may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the same quality then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business, financial condition and results of operations.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval and similar foreign notifications and approvals. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

Risks related to government regulation

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, the EMA or comparable foreign regulatory authorities must also approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. We do not have any product candidates approved for sale in any jurisdiction, including in 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, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, distribution, AE reporting, advertising, promotion, sampling, import, export, 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. In addition, we will be subject to continued compliance with cGMP and GCP (and comparable) requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, EMA and other comparable regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application and previous responses to inspection observations. 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.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or other comparable regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us or suspension or withdrawal of approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

Additionally, sponsors of approved drugs and biologics must provide notice to the FDA of any changes in marketing status, such as the withdrawal of a drug. Manufacturers are also required to notify FDA for discontinuing or interrupting supply of certain drugs, and failure to do so could result in a letter citing such failure to comply and public posting of such letter and redacted company response which could damage the company's reputation. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The policies of the FDA, EMA and other comparable 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 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 lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of any product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

We may pursue orphan drug designation for certain of our product candidates, and we may not be able to obtain such designation, or obtain or maintain the benefits of such designation including orphan drug exclusivity, and even if we do, that exclusivity may not prevent regulatory authorities from approving other competing products.

We intend to seek orphan drug designation for some of our other product candidates; however, we may never receive such designations. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. Orphan drug designation must be requested before submitting an NDA. A similar regulatory scheme governs orphan products in the EU.

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 candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same product for the same therapeutic indication for seven years.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition and indication. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same approved use or indication if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs relating to the relevant approved use or indication of the patients with the rare disease or condition. Further, 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.

The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

In the EU, orphan designation is granted by the European Commission based on a scientific opinion of the EMA's Committee for Orphan Medicinal Products. 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 5 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 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 requirement 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. However, during such period, marketing authorizations may be granted to a similar medicinal product with the same orphan indication if: (i) the applicant can establish that the second medicinal product, although similar to the orphan medicinal product already authorized is safer, more effective or otherwise clinically superior to the orphan medicinal product already authorized; (ii) the marketing authorization holder for the orphan medicinal product grants its consent; or (iii) if the marketing authorization holder of the orphan medicinal product is unable to supply sufficient quantities of product. 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).

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

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

For example, we may seek a Fast Track Designation for future product candidates we develop. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. Fast Track Designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a NDA is submitted, the application may be eligible for priority review. A NDA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot be certain that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development activities.

We may seek Breakthrough Therapy Designation for any product candidate that we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs and biologics designated as Breakthrough Therapies also receive the same benefits associated with Fast Track Designation, including eligibility for rolling review of a

submitted NDA, if the relevant criteria are met. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval and priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if any product candidate we develop qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Even in the absence of obtaining Fast Track and/or Breakthrough Therapy Designations, a sponsor can seek priority review at the time of submitting a marketing application. The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months. Priority review designation may be rescinded if a product no longer meets the qualifying criteria.

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

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for our one or more of our therapeutic candidates from the FDA, EMA, or other comparable regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a therapeutic candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the therapeutic candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Under the Food and Drug Omnibus Reform Act (the "FDORA"), the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send status updates on such studies to the FDA every 180 days to be publicly posted by the agency, or if such post-approval studies fail to verify the drug's predicted clinical benefit. The FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress.

Prior to seeking accelerated approval, we would seek feedback from the FDA, EMA, or other comparable regulatory authorities and would otherwise evaluate our ability to seek and receive such accelerated approval.

There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA, or other comparable regulatory authorities, we will continue

to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway and subsequently converted by FDA to full approval. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our therapeutic candidate would result in a longer time period to commercialization of such therapeutic candidate, could increase the cost of development of such therapeutic candidate and could harm our competitive position in the marketplace.

If we are required by the FDA to obtain approval of a companion diagnostic in connection with approval of any of our product candidates, and we do not obtain, or face delays in obtaining, FDA approval of such companion diagnostic, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Depending on the data from our clinical trials, we may decide to collaborate with diagnostic companies during our clinical trial enrollment process to help identify patients with characteristics that we believe will be most likely to respond to our product candidates. If a satisfactory companion diagnostic is not commercially available in this situation, we may be required to develop or obtain such test, which would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities. The approval or clearance of a companion diagnostic as part of the therapeutic product's further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect.

If the FDA or a comparable foreign regulatory authority requires approval or clearance of a companion diagnostic for any of our product candidates, whether before or after the product candidate obtains regulatory approval, we and/or third-party collaborators may encounter difficulties in developing and obtaining approval or clearance for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of the relevant product. We or our collaborators may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidates, if approved, on a timely or profitable basis, if at all.

If we fail to maintain necessary regulatory clearance for our Prolaio platform, which includes features that are regulated by the FDA and which may be regulated in foreign jurisdictions as medical devices, or if clearances or approvals for future devices and indications are delayed or not issued, our commercial operations would be harmed.

Our Prolaio platform currently includes features that are regulated by the FDA and which may be regulated in foreign jurisdictions as medical devices. Changes to our Prolaio platform could be subject to extensive medical device regulation by the FDA in the United States and outside the United States. Government regulations specific to medical devices are wide-ranging and govern, among other things:

- device design, development and manufacture;
- laboratory, preclinical and clinical testing, labeling, packaging, and storage;
- premarket clearance or approval;
- record keeping;
- device marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths and serious injuries and recalls and correction and removals.

Any failure to obtain further 510(k) clearances or any required foreign marketing authorizations may add significant time and expense to our regulatory clearance and marketing process, may delay our ability to generate revenue, and may have a negative impact on our stock price. We may not be able to obtain or maintain the necessary clearances, approvals, or authorizations necessary to market the Prolaio platform for specific indications inside or outside the United States or such approvals, clearances, or authorizations may be unduly delayed, which could harm our business. Additionally, if the FDA rejects our 510(k) submissions for specific indications, we may be required to obtain FDA authorization through the de novo pathway, which will require additional time and resources, including potentially the need to conduct additional clinical trials to demonstrate safety and effectiveness of our candidate device.

Moreover, the FDA may not approve or clear our 510(k), de novo request, or premarket approval (" PMA") applications and foreign regulatory authorities may not authorize our applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business operations and financial condition. The FDA or foreign regulatory authorities may also change authorization, clearance and approval policies, adopt additional regulations or revise existing regulations, or take other action which may prevent or delay approval or clearance of our products under development. Any of these actions could have a material adverse effect on our business operations and financial condition.

Certain features of our Prolaio platform that are solely intended to transfer, store, convert formats, or display medical device data or results are listed with the FDA as a Class I, 510(k)-exempt, medical device data system. From time to time, the FDA may disagree with the classification regulation under which a registrant lists their device. For example, the FDA may disagree with a registrant's determination to classify their device as a Class I medical device. Instead, the FDA may determine the device to be a Class II or Class III device requiring the submission of a 510(k) or PMA application for premarket clearance or approval. In the event that the FDA determines that our devices, whether by functionality or marketing claims, exceeds the limitations on 510(k)-exemption such that premarket clearance or approval is required (i.e., that our device is intended for a use different from the intended use of a legally marketed device in the generic type of device under the applicable classification regulation or that our modified device operates using a different fundamental scientific technology than such a legally marketed device), should be classified as Class II devices or Class III devices requiring premarket clearance or approval, or should the FDA decide to reclassify our device as a Class II or Class III device requiring premarket clearance or approval, we could be precluded from marketing our devices for clinical use within the United States for months or longer depending on the requirements of the classification. Obtaining premarket clearance or approval could significantly increase our regulatory costs, including expense associated with potentially required preclinical studies and clinical trials, more extensive testing and other costs.

We are subject to ongoing and extensive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration, and listing of devices. For example, medical device manufacturers must submit certain reports to the FDA and keep required records as a condition of obtaining and maintaining marketing authorization. These reports include information about failures and certain AEs potentially associated with the device after its marketing authorization. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

The FDA and the U.S. Federal Trade Commission (the "FTC") also regulate the advertising and promotion of our devices to ensure that the claims we make are consistent with our regulatory clearances or approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or the FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including FDA warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions, among others:

- adverse publicity, warning letters, fines, injunctions, consent decrees, and civil penalties;
- obligations to repair, replace, refund, or recall our marketed devices, or government seizure of them;
- operating restrictions, partial suspension, or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new devices, new intended uses or modifications to existing devices;

- withdrawing premarket approvals that have already been granted or reclassifying our devices; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition would be harmed.

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

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, marketing personnel, third-party payors, patient organizations and customers expose us to broadly applicable foreign, federal and state 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 any product for which we obtain regulatory approval.

Efforts to ensure that our current and future business arrangements both internally and with third parties will comply with applicable healthcare laws and regulations will involve ongoing substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices, including certain consulting agreements and advisory board agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. These laws include federal and state anti-kickback laws, false claims statutes, civil monetary penalties laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers, and laws related to price reporting. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices may be challenged under one or more of these laws. Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical and medical technology companies to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would sell, market and distribute our products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource-consuming and can divert a company's attention from the business.

It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, such as Medicare and Medicaid integrity oversight and reporting obligations, contractual damages, individual imprisonment, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business 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. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to reward improper performance generally is typically governed by the national anti-bribery laws of EU Member States and the Bribery Act 2010 in the United Kingdom. Infringement of these laws could result in substantial fines and imprisonment. EU Directive

2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the United Kingdom despite its departure from the European Union.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The successful commercialization of any of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors, including governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors. Our ability to achieve coverage and acceptable levels of reimbursement for our product candidates by third-party payors will have an effect on our ability to successfully commercialize those products. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which products and services they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product or service is:

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

In the United States, no uniform policy of coverage and reimbursement for products and services exists among all third-party payors. As a result, obtaining coverage and reimbursement approval of a product or service from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products or services on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Furthermore, rules and regulations regarding reimbursement change frequently, and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely.

Third-party payors increasingly are challenging prices charged for medical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular technologies or drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and offer to reimburse patients only for a less expensive competitor product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our product candidates, pricing of existing products and services may limit the amount we will be able to charge for our products and services. These payors may deny or revoke the reimbursement status of a given product or service, or establish prices for new or existing marketed products or services at levels that are too low to enable us to realize an appropriate return on our investment in product development. If

reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop.

Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Private payors tend to follow the coverage and reimbursement policies established by the U.S. Centers for Medicare & Medicaid Services (the "CMS") which determines whether and to what extent a new medicine will be covered and reimbursed under Medicare. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations, or other ancillary services required following the use of product candidates, once approved. Some third-party payors may require pre-approval of coverage or implement prior authorization or step therapy programs for new or innovative drug therapies or services before they will reimburse patients who use such therapies which may become time-consuming or costly for patients and lead to a reduction in revenue. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Net prices for certain products, especially for drug products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future changes to laws. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers are required to calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Moreover, increasing efforts by governmental and other third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. If, for example, we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions and fines should we be found to be in violation of any applicable obligations thereunder. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of our product candidates, if any, may be.

In addition, in some foreign countries, the proposed pricing for a product must be approved before it may be lawfully marketed. The requirements governing product pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or

reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations and increase the difficulty and cost for us to obtain coverage for and commercialize any of our current or future product candidates and may adversely affect the prices we may set.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (1) changes to our manufacturing arrangements, (2) additions or modifications to product labeling, (3) the recall or discontinuation of our products or (4) additional record-keeping requirements. As a company developing both pharmaceutical products and utilizing medical device technology through our acquisition of Prolaio, we may be subject to healthcare reform measures affecting both drug and device manufacturers. If any such changes were to be imposed, they could adversely affect the operation of our business.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. For instance, the Inflation Reduction Act of 2022 (the "IRA") includes several provisions that will impact our business to varying degrees, including provisions that allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, among others. Depending upon the implementation of this program, these price-negotiation provisions may have a negative impact on our future revenue and profits. Further, the IRA imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The implementation of the IRA is currently subject to ongoing litigation that challenges the constitutionality of the IRA's drug price negotiation program provisions. The outcome of this litigation as well as the effects of the IRA on the pharmaceutical industry cannot yet be fully determined but is likely to be significant. Additional drug pricing proposals could appear in future legislation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our revenue generated from the sale of any approved products.

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 commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Congress has indicated that it will continue to seek new legislative measures to control drug costs. Most recently, the current administration has pursued a multi-pronged most-favored-nation ("MFN") drug pricing strategy that could materially affect our ability to generate revenue from our product candidates, if approved. This strategy includes the May 12, 2025 Executive Order directing HHS to communicate MFN price targets to manufacturers, resulting in voluntary MFN pricing agreements between the administration and 17 major manufacturers (committing to Medicaid price parity, MFN pricing on new launches, and participation in TrumpRx.gov in exchange for tariff relief and regulatory benefits); CMS's proposed mandatory GLOBE (Medicare Part B) and GUARD (Medicare Part D) payment models that would impose incremental rebate obligations on manufacturers of qualifying single-source drugs in specified therapeutic categories, and a voluntary Medicaid MFN model (GENEROUS). Legislative proposals, including the "Most Favored Patient Act" introduced in March 2026, seek to codify these initiatives. It is unclear whether these proposals will survive legal challenge (a prior MFN model was halted by federal courts and rescinded); but, this movement represents an evolving area of uncertainty that could materially adversely affect our pricing strategy and revenue, if our product candidates are approved and achieve commercial scale.

At the state level, state governments have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding

procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for any of our current and future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies, and additional downward pressure on the price that we receive for any approved product candidate for which we may obtain regulatory approval, and the frequency with which any such product candidate is prescribed or used. The implementation of cost containment measures, changes in healthcare spending and policy, or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, and materially affect our business, if approved. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

Our employees, independent contractors, consultants, third-party manufacturers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our current and any future employees, independent contractors, consultants, contract manufacturers, and vendors. Misconduct by these parties could include intentional, reckless, and/or negligent conduct that fails to comply with FDA or other regulations, provide true, complete and accurate information to the FDA, EMA, and other comparable regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations, and prospects, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve

allegations of non-compliance with these laws and curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

Off-label use or misuse of our product candidates may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits.

If our product candidates are approved by the FDA, we may only promote or market our product candidates in a manner consistent with their FDA-approved labeling. We will train our marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our product candidates off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. The use of our product candidates for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our product candidates for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation.

Inadequate funding for the FDA or other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

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

Disruptions at the FDA or other comparable regulatory authorities or government agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical 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, 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, including as a result of reaching the debt ceiling, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

EU medicine marketing and reimbursement regulations may materially affect our ability to market and obtain reimbursement for our products in the EU Member States.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to reward improper performance generally is typically governed by the national anti-bribery laws of EU Member States and the Bribery Act 2010 in the United Kingdom. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in

kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the United Kingdom despite its departure from the European Union.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in some foreign countries, including some countries in the European Union, the proposed pricing for a product must be approved before it may be lawfully marketed. The requirements governing product pricing and reimbursement vary widely from country to country. For example, some EU Member States may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and control the prices of such products. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU Member States, can further reduce prices. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

We are subject to export and import controls, economic sanctions, and anti-corruption laws and regulations of the United States and other jurisdictions. We can face criminal liability and other serious consequences for violations of these laws and regulations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control. Export controls and trade sanctions laws and regulations may restrict or prohibit altogether the provision, sale, or supply of our products to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo. We are also subject to anti-corruption and anti-bribery laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, and other state and national anti-bribery laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

If we or any third-party manufacturer we engage now or in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could have a material adverse effect on our business.

We and third-party manufacturers we engage now are, and any third-party manufacturer we may engage in the future will be, subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our

use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

Risks related to our intellectual property

Our success depends upon our ability to obtain and protect our intellectual property and proprietary information. If we or our licensors are unable to obtain, maintain, defend and enforce patent or other intellectual property protection for any of our current or future product candidates or platform technologies, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad or enforceable, third parties could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any of our current or future product candidates and platform technologies may be adversely affected.

We rely, and may in the future rely, upon a combination of patents, know-how, trademarks, trade secrets, and confidentiality agreements, to protect the intellectual property related to our current and future product candidates and proprietary platform technologies to prevent third parties from exploiting our achievements, thus eroding our competitive position in our market. We also rely on protection afforded by in-licensed intellectual property rights and proprietary technology of third parties. Our success depends in large part on our ability to obtain, maintain, expand, enforce, and defend the scope, ownership or control, validity and enforceability of our intellectual property protection in the United States and other countries with respect to any of our current and future product candidates and other proprietary platform technologies we may develop, as well as our ability to operate without infringing the proprietary rights of others. We generally seek, and may in the future seek, to protect our proprietary position, in part, by filing patent applications in the United States and abroad relating to any of our current and future product candidates and platform technologies, manufacturing processes and methods of use. We also seek to protect, and may seek to protect, our proprietary position by in-licensing or acquiring in the future relevant issued patents, pending patent applications and proprietary technologies from third parties. We will endeavor to seek additional patent protection to cover proprietary features of our product candidates, platform technologies and novel discoveries that are important to our business. Some of our in-licensed patent families were drafted, filed, and prosecuted by our licensors and even where we now control the right to prosecution under the applicable license agreements, we are still required to solicit input and consider comments from such licensors. Additionally, some of our owned and in-licensed patent families are in an early stage of prosecution and cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents are issued from such applications, and then only to the extent the issued claims cover the third parties' activities. Our ability to stop third parties from making, using, selling, marketing, offering to sell, importing and commercializing any product candidates or platform technologies we may develop is dependent upon the extent to which our products are covered by valid and enforceable patents or are effectively maintained as trade secrets. If we are unable to obtain, maintain, expand, enforce and defend the scope, ownership or control, validity and enforceability of our intellectual property protection, our business, financial condition, results of operations and prospects could be materially harmed.

Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our intellectual property, obtain, maintain, expand, enforce and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patent applications we currently or may in the future pursue or may in-license will issue as patents in any particular jurisdiction, whether the claims of any issued patents will provide sufficient protection against competitors or other third parties, or if these patents are challenged by our competitors, whether the patents will be found to be invalid,

unenforceable, or not infringed or not owned or controlled by us. The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, defend or license all necessary or desirable patent applications or patents at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we or our licensors will fail, or previously failed, to identify patentable aspects of research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, licensees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third party from using any of our technology that is in the public domain from competing with any of our current or future product candidates or platform technologies. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable in light of the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to invent the inventions claimed in any of our owned or in-licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to invent or the first to file for patent protection of such inventions, our owned or in-licensed patents and patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable.

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. As a result, the issuance, scope, validity, enforceability, and commercial value of our owned and in-licensed patent rights are highly uncertain. Our current and future patent applications may not result in patents being issued.

Further, even if patents are granted, they may not afford sufficient protection of any of our current or future product candidates or proprietary platform technologies or their intended uses against competitors, nor can there be any assurance that the issued patents cannot be designed around, invalidated by third parties, or effectively prevent others from commercializing competitive products or technologies to any of our current or future product candidates or platform technologies. Furthermore, even if granted, the resulting patents may be difficult to enforce. Obtaining and maintaining our owned and in-licensed patent protection depends on compliance with various procedural, document submission, information disclosure, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. If we experience noncompliance events that cannot be corrected and we lose our patent rights, competitors could enter the market, which would have a material adverse effect on our business. Further, any issued patents that we own or license or may own or license in the future covering any of our current or future product candidates or platform technologies could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or other countries, including the U.S. Patent and Trademark Office (the "USPTO"). Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting. In certain circumstances, the finding could be cured by filing a retroactive terminal disclaimer over unexpired reference patent(s), which would result in a reduction of patent term, including a reduction or loss of a patent term adjustment granted by the USPTO. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Also, patent terms, including any extensions or adjustments that may or may not be available to us, may not protect our competitive position on any of our current or future product candidates or platform technologies for an adequate amount of time, and we may be subject to claims challenging the inventorship, ownership, validity, enforceability of our owned or in-licensed patents and/or other intellectual property. Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect any of our current or future product candidates or platform technologies. Further, if we encounter delays in our development and testing, clinical trials or regulatory review and approval of any of our current or future product candidates, the period of time during which we could market such product candidates under patent protection may be reduced, since any patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. Thus, our owned and in-licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or afford us any meaningful competitive advantage.

Moreover, the claim coverage in a patent application can be significantly reduced before the corresponding patent is granted. Even if owned or in-licensed patent applications issue as patents, they may not issue in a form that will provide us

with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents issuing from our owned and in-licensed patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether any of our current or future product candidates and other proprietary platform technologies will be protectable or remain protected by valid and enforceable patents. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. Furthermore, our competitors or other third parties may avail themselves of safe harbors under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") to conduct research and clinical trials.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability, and our owned or in-licensed patent rights may be challenged in the courts or patent offices in the United States and abroad. We may be subject to post-grant proceedings at the USPTO challenging the validity of one or more claims of our owned and in-licensed patents. Third-party submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on our pending patent application or patent application we may license in the future. A third party may also claim that our owned and in-licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In addition, we or our licensors may become involved in opposition, derivation, revocation, reexamination, reissue, interference, inter partes review, post-grant review proceedings or other similar proceedings in the United States and/or foreign jurisdictions challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned or in-licensed patent rights, and may allow third parties, including generic drug companies, to commercialize any of our current or future product candidates and use any other proprietary platform technologies we may develop to compete directly with us.

Moreover, some of our owned or in-licensed patent rights are co-owned with third parties or subject to third party rights under the Bayh-Dole Act of 1980, and our future owned or in-licensed patent rights may be co-owned with third parties or subject to third party rights. For instance, at least a portion of the patent rights in our Prolaio patent portfolio and at least a portion of the patent rights in-licensed from Mayo may be subject to a U.S. government agency's "March-in rights" under 35 U.S.C. §§200-212, and certain preclinical stage product candidates in-licensed from BMS Co. are co-owned by BMS Co. and a university and exclusively licensed to us from BMS Co. In the United States, each co-owner has the freedom to license and exploit the technology. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patent rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of such patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, or if any of our material license agreements are terminated, we could lose our rights to key intellectual property and components enabling our technologies.

Our commercial success will heavily depend on the maintenance of our license agreements. We are a party to license agreements with Ionis, MyoKardia, BMS Co., Sanofi, and Mayo that are important to our business. If, for any reason, our license agreements are terminated or we otherwise lose some or all of the rights under such agreements, it would adversely affect our business. For example, pursuant to our license agreements with Mayo, MyoKardia, BMS Co. and Ionis, we have exclusive and worldwide rights to develop and commercialize our product candidates, impose, and future agreements may impose, various development, diligence, commercialization, milestone payment, royalty and other obligations on us and require us to meet development, regulatory or commercialization timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. If we fail to satisfy any obligations under such license agreements, the applicable licensor may terminate our license, which could have a material adverse effect on us.

The agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. For example, disputes may arise regarding the payment of the royalties or other payments due to licensors in connection with the rights we

license from them. Licensors may contest the basis of such payments, including the royalties we retained and claim that we are obligated to make payments under a broader basis. In addition, disputes may arise between us and our current or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties under our license arrangements;
- our right to transfer or assign the license;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our financial or other obligations under the license agreement;
- the priority of invention of patented technology; and
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners.

Such disputes may be costly to resolve and may divert management's attention away from day-to-day activities. In addition to the costs of any litigation we may face, any legal action against us could increase our payment obligations under the respective agreement and require us to pay interest and potentially damages to such licensors. If disputes over intellectual property that we have in-licensed, or in-license in the future, prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates or platform technologies, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Despite our best efforts, our current or future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products, if approved, and technology covered by these license agreements. Such termination would result in the ability of the prior licensor to assert the prior licensed patents against us, or the prior licensor could license the patents to a competitor who could assert the prior licensed patents against us. As a result, we may be required to cease our development, manufacture and commercialization of our product candidates and use of our proprietary platform technologies covered by the patent rights owned by the licensors, which could have a material adverse effect on us. Alternatively, the prior licensor could abandon the patent rights, which would reduce the barrier to entry into the market. If these in-licenses are terminated, or if the in-licensed patents fail to provide the intended exclusivity, and if competitors circumvent any regulatory exclusivity, competitors would have the freedom to market products identical to ours. These events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. For example, we may agree to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects, and we may be required to identify and license replacement technology from third parties, which may not be available on reasonable terms, if at all.

Further development of our proprietary platform technologies and product candidates may require us to enter into additional license or collaboration agreements. Our future licenses may not provide us with commercially reasonable terms, exclusive rights to use the licensed intellectual property and technology, or exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates and platform technologies in the future.

We may in the future enter into collaborations and further strategic alliances to maximize the potential of our product candidates or platform technologies, and we may not realize the anticipated benefits of such collaborations or alliances. We may continue to form collaborations or alliances in the future with respect to any of our current or future product candidates or platform technologies, but may be unable to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

We have entered into license agreements, and may in the future seek to enter into collaborations, strategic alliances, joint ventures, additional licenses and other similar arrangements for the development or, if approved, commercialization of any of our current and future product candidates due to capital costs required to develop or commercialize such product candidates or otherwise. We may not be successful in our efforts to establish or maintain collaborations or other similar arrangements because our research and development pipeline may be insufficient, future product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view any of our current or future product candidates as having the requisite potential to demonstrate safety and potency (or efficacy), or significant commercial opportunity.

We may have conflicts with our future collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations, or the ownership of intellectual property developed during our collaboration. Moreover, a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products. If any conflicts arise with any of our future collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenue: disputes regarding milestone payments or royalties; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of a product candidate, including providing us with data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex. Even if we are successful in our efforts to establish or maintain such collaborations, the terms that we agree upon may not be favorable to us. As a result, we may need to relinquish valuable rights to our future revenue streams, research and development programs, intellectual property, any of our current or future product candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. In addition, our future collaborations may limit our control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of any of our current or future product candidates. Our ability to generate revenue from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a collaboration, license, or strategic transaction, we will achieve an economic benefit that justifies such transaction, and such transaction may not yield additional development product candidates for our pipeline. Furthermore, we may not be able to maintain such collaborations if, for example, the development or approval of any current or future product candidates are delayed, the safety of any such product candidate is questioned, or the sales of any of our current or future product candidates, if approved, are unsatisfactory.

In addition, future collaborations may be terminable by our collaborators and strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and, if approved, commercialization of any of our current or future product candidates, and may not conduct those activities in the same manner as we do. Any termination of our collaborations we enter into in the future, or any delay in entering into collaborations related to any of our current or future product candidates, could delay the development and, if approved, commercialization of such product candidates, and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Filing, prosecuting, maintaining, enforcing and defending patents on any of our current or future product candidates or platform technologies in all countries throughout the world is expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Prosecution of foreign patent applications is often a longer process, and patents may grant at a later date, and with a shorter term, than in the United States. The requirements for patentability differ in certain jurisdictions and countries. Additionally, the patent laws of some countries do not afford intellectual property protection to the same extent as the laws of the United States. For example, other countries may impose substantial restrictions on the scope of claims, including limiting patent protection to specifically disclosed embodiments. 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 intellectual property in and into the United States or other jurisdictions. Competitors may use our intellectual property in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export 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 products, and our current or future owned and in-licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our owned and in-licensed patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan and China, may have a heightened standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Proceedings to enforce our owned and in-licensed intellectual property and proprietary rights in the United States or other jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our current patents and any patents we may own or license in the future at risk of being invalidated or interpreted narrowly, could put our owned and in-licensed 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 owned and in-licensed intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Many countries have compulsory licensing laws under which a patent owner or exclusive licensee may be compelled to grant licenses to third parties, including governmental agencies. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner or exclusive licensee may have limited remedies, which could materially diminish the value of such patent protection. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. In addition, geo-political actions in the United States and in foreign countries (such as the Russia and Ukraine conflict) could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any licensors and the maintenance, enforcement or defense of our issued patents which could impair our competitive intellectual property position. For example, the United States and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia.

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

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

The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some, but not all cases, for example in China and India, a foreign filing license cannot be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We may also be dependent on licensors to take the necessary actions to comply with these requirements with respect to our in-licensed intellectual property.

Public health pandemics (such as the COVID-19 pandemic), geopolitical instability (war and terrorism), natural disasters, or similar events may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for any of our current and future product candidates or platform technologies.

Changes in patent laws or their interpretations could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States or in other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the "America Invents Act") enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us or our licensors could therefore be awarded a patent covering an invention of ours or our licensors even if we or our licensors had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors are the first to either (i) file any patent application related to any of our current or future product candidates and other proprietary platform technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our owned or in-licensed patent claims or any patent claims we may license in the future that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. We cannot predict how decisions by the courts, the U.S. Congress or the USPTO may impact the value of our owned and in-licensed patent rights. For example, the U.S. Supreme Court held in *Amgen v. Sanofi* (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. As such, our owned and in-licensed patent rights that grant with functional claims may be vulnerable to third party challenges seeking to invalidate these claims for lacking enablement or adequate support in

the specification. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. In addition to heightened patentability requirements, the Supreme Court and Federal Circuit's interpretation of biosimilar product approval under the Biologics Price Competition and Innovation Act, has evolved in recent years, affecting the "patent dance" provisions of the statute, which are intended to resolve any patent infringement issues before the approval of a biosimilar. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have or may obtain or license in the future.

In 2012, the European Union Patent Package (the "EU Patent Package") regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (the "UPC") for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023, and has become a common forum for challenging 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, unless otherwise opted out. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patents and 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. We may decide 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 current and future platform technologies and any of our current and future product candidates due to increased competition and, resultantly, on our business, financial condition, results of operations and prospects. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is limited precedent for the court, increasing the uncertainty of any litigation in the UPC.

Issued patents covering any of our current or future product candidates or platform technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Our owned and in-licensed patent rights may be subject to priority, validity, inventorship, ownership and enforceability disputes. Legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time-consuming and likely to divert significant resources from our core business, including distracting our management and scientific personnel from their normal responsibilities and generally harm our business. If we or any of our licensors are unsuccessful in any of these proceedings, such patents and patent applications may be narrowed, invalidated or held unenforceable. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we initiate legal proceedings against a third party to enforce a patent covering any of our current or future product candidates or platform technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, lack of sufficient written description, failure to claim patent-eligible subject matter or obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading or inconsistent statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, shortening the term of or amendment to our owned or in-licensed patent rights or any patent rights we may obtain or license in the future in such a way that they no longer cover any of our current or future product candidates or platform technologies or prevent third parties from competing with our product candidates or platform technologies. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensors and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for any of our current or future product candidates or platform technologies. There is also a risk that, even if the validity of such patents is upheld, the court will construe the

patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our owned and in-licensed patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e). Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect the competitive position of any of our current or future product candidates or platform technologies for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering any of our current or future product candidates or platform technologies are obtained, once the patent has expired, we may be vulnerable to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of any of our current or future product candidates or platform technologies, patents protecting such product candidates or platform technologies might expire before or shortly after such product candidates or platform technologies 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 our product candidates or platform technologies. If we do not have sufficient patent life to protect our products, our business, financial condition, results of operations and prospects will be adversely affected.

If we do not obtain patent term extension and equivalent extensions outside of the United States for any of our current or future product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA regulatory approval of any of our current or future product candidates, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it or a method of manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate. However, we may not be granted an extension for various reasons, including failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or failing to satisfy other applicable requirements. Moreover, the applicable time period afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we may license from a third party in the future, we may need the cooperation of that third party. If we are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

We or our licensors may be subject to claims challenging the inventorship or ownership of our owned and in-licensed patents and other intellectual property.

We or our licensors may be subject to claims that former employees, consultants, licensees, collaborators or other third parties have an interest in our owned or in-licensed patent rights, trade secrets, or other intellectual property as an inventor, co-inventor or owner of trade secrets. For example, we or our licensors may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing any of our current or future product candidates and other proprietary platform technologies we may develop. We or our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as from a government entity, such that we or our licensors are not the sole and exclusive owners of the patents we in-licensed. The failure to name the proper inventors on a patent application can result in the patents issuing therefrom being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or platform technologies or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our owned or in-licensed patent rights, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as ownership of, or the right to use intellectual property that is important to any of our current or future product candidates and

other proprietary platform technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In addition to seeking patent protection for any of our current or future product candidates and proprietary platform technologies, we may rely on trade secret protection and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, licensees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Trade secrets and know-how can be difficult to protect. We cannot guarantee that we have entered into applicable agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. 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. We cannot guarantee that any potential trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret (such as through a cybersecurity breach) is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, others may independently discover similar trade secrets and proprietary information. If any of our trade secrets were to be disclosed or misappropriated or if any such information were to be independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed. Additionally, we may need to share our proprietary information, including trade secrets, with current or 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 foreign actors, and those affiliated with or controlled by state actors.

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

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

Some of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer, or that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we

regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market any of our current or future product candidates or platform technologies.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are or will be complete or thorough, nor can we be certain that we or our licensors have identified or will identify each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of any of our current or future product candidates or platform technologies in any jurisdiction. Patent applications in the United States and elsewhere are not published until 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. Therefore, patent applications covering any of our current or future product candidates or platform technologies could have been filed by others without our knowledge. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that any of our current or future product candidates or platform technologies 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. Alternatively, we may incorrectly determine that the Hatch-Waxman Amendments are a defense for a safe harbor to infringement of a patent we consider relevant to the research or clinical development of any of our current or future product candidates. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market any of our current or future product candidates or platform technologies. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our current or future product candidates or platform technologies that are held to be infringing. We might, if possible, also be forced to redesign any of our current or future product candidates or platform technologies or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Third-party claims of intellectual property infringement, misappropriation, or other violations against us or our collaborators could be expensive and time-consuming and may prevent or delay the development and commercialization of any of our current or future product candidates or platform technologies.

Our commercial success depends in part on our and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post-grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we plan to commercialize our programs (including product candidates and platform technologies) and in which we are developing other proprietary technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our programs and

commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot guarantee that our product candidates, platform technologies and other proprietary technologies we develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued for which a third party, such as a competitor in the fields in which we are developing our product candidates, platform technologies and other proprietary technologies, might assert as infringed by us. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to any of our current or future product candidates. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe. For example, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover any of our current or future product candidates or platform technologies or the use of any such product candidates or platform technologies.

If any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court could hold that such patents are valid, enforceable and infringed by us. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. If a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Such licenses may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms or at all, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. In addition, we may in the future pursue patent challenges with respect to third-party patents, including as a defense against the foregoing infringement claims. The outcome of such challenges is unpredictable.

Even if resolved in our favor, the foregoing proceedings could be very expensive, particularly for a company of our size, and time-consuming. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Such proceedings may also absorb significant time of our technical and management personnel and distract them from their normal responsibilities. Uncertainties resulting from such proceedings could impair our ability to compete in the marketplace. 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. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

Third parties, such as competitors, may infringe our owned or in-licensed patent rights. In an infringement proceeding, a court may decide that a patent we own or in-license is invalid or unenforceable or may refuse to stop the other party from using the invention at issue. In addition, our owned or in-licensed patent rights may become involved in inventorship, ownership, priority, enforceability, or validity disputes. To counter or defend against such claims can be expensive and time-consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and proceedings, there is a risk that some of our confidential information could be compromised by disclosure during such litigation and proceedings.

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

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing, misappropriating or violating 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 the markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. If our trademarks are successfully challenged or determined to be infringing, misappropriating or violating other marks, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we may propose to use with any of our current or future product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe, misappropriate or otherwise violate the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to obtain, protect or enforce our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement, misappropriation, dilution or other claims brought by owners of other registered 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. Our efforts to obtain, enforce or protect our proprietary rights related to trademarks, trade names, domain name, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar or identical to any of our current or future product candidates or utilize similar technology but that are not covered by the claims of the patents that we currently or may in the future own or in-license;
- we or our licensors or collaborators might not have been the first to make the inventions covered by our current or future patent applications;
- we or our licensors or collaborators might not have been the first to file patent applications covering our or their 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 and future patent applications that we own or may license will not lead to issued patents;
- any issued patent that we own or license in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- our competitors or other third parties might conduct research and development activities in countries where we or our licensors 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;
- we may fail to identify potential patentable subject matter and/or may fail to file on it;
- the patents or other intellectual property rights of others may harm our business; and
- we may choose not to file for patent protection to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property or disclose information resulting in a loss of protection for such trade secret.

Should any of the foregoing occur, it could adversely affect our business, financial condition, results of operations and prospects.

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

The growth of our business may depend in part on our ability to acquire, in-license or use third-party intellectual property and proprietary rights. For example, any of our current or future product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing our compounds and pre-existing pharmaceutical compounds, we may develop combination therapies with our compounds and third-party compounds, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patent or other intellectual property rights we may co-own with third parties, we may require licenses to such co-owners' interest to such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe, misappropriate or otherwise violate those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we can obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

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

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

Risks related to ownership of our common stock

The price of our common stock may be volatile, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

The trading price of our common stock may be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- the commencement, enrollment, completion or results of our current or future preclinical and clinical trials for our product candidates;
- any delay in identifying and advancing a clinical candidate for our other programs;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays, suspensions or terminations in future preclinical studies or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates or the failure of a regulatory authority to accept data from preclinical studies or clinical trials conducted in other countries;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to any of our current or future product candidates;
- introduction of new products, product candidates or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position and cash burn rate;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of the healthcare payment systems;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs, reputational harm and a diversion of management's attention and resources.

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

Our quarterly and annual operating results may fluctuate significantly, due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and, if approved, commercialization activities relating to our current and future product candidates, which may change from time to time;
- the timing and status of enrollment for clinical trials;
- the cost of manufacturing our product candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- timing and amount of any milestone, royalty or other payments due under any collaboration, license or purchase agreement;
- future accounting pronouncements or changes in our accounting policies;
- 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 partners;

- the timing of receipt of approvals for our product candidates from regulatory authorities in the United States and internationally;
- exchange rate and interest rate fluctuations;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products; and
- the level of demand for our product candidates, if approved, which may vary significantly over time.

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 industry or financial analysts or investors for any period. If our future revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if any 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.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. Similarly, if one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our executive officers, directors, principal stockholders and their respective affiliates own a significant percentage of our common stock and have the ability to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, five percent stockholders and their affiliates beneficially own a significant percentage of our common stock. As a result, these stockholders, if acting together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. In addition, certain of our principal stockholders, including ARCH Venture Fund XIII, L.P. and Perceptive Capital Solutions Holding LP, have designated certain members of our board of directors. The interests of these stockholders may not be the same as or may even conflict with the interests of our other stockholders. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Sales of a substantial number of shares of our common stock in the public market could cause our common stock price to drop significantly, even if our business is performing 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 holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

As of June 30, 2026, we had 93,467,940 shares of common stock outstanding. Of these shares, the 28,750,000 shares sold in our IPO may be resold in the public market immediately. The resale of certain shares of our outstanding common stock is currently restricted under securities laws or as a result of lock-up or other agreements, but will be able to be sold after the expiration of the lock-up in November 2026 and termination of restrictions under securities laws. Moreover, certain holders of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject

to volume limitations applicable to affiliates and lock-up agreements. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.
In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

Issuance of capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

We do not currently intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value for our common stock, which is not certain.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Our third amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of not less than two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our third amended and restated certificate of incorporation or amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person

acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

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

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our third amended and restated certificate of incorporation or our amended and restated bylaws (including the interpretation, validity or enforceability thereof) or (iv) any action asserting a claim that is governed by the internal affairs doctrine (the "Delaware Forum Provision"). The Delaware Forum Provision does not apply to any causes of action arising under the Securities Act or the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act or the Exchange Act (the "Federal Forum Provision"). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. While the Delaware Supreme Court and other state courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act or Exchange Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the U.S. may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

We may not be able to maintain a listing of our common stock on Nasdaq.

We must meet certain financial and liquidity criteria to maintain a listing of our common stock on Nasdaq. If we violate Nasdaq's listing requirements, our common stock may be delisted. If we fail to meet any of Nasdaq's listing standards, our common stock may be delisted. The delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of our stockholders' investment.

The structure of our common stock may limit the ability of certain stockholders to influence corporate matters and may limit such stockholders' visibility with respect to certain transactions.

The structure of our common stock may also limit the ability of certain stockholders to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. We do not currently have any shares of non-voting common stock outstanding. Nonetheless, we may issue non-voting common stock in the future and each outstanding share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our third amended and restated certificate of incorporation. Consequently, if holders of our non-voting common stock, if any, in the future exercise their option to make this conversion, this will have the effect of increasing the relative voting power of such holders of our non-voting common stock, and correspondingly decreasing the voting power of all other holders of our common stock, which may limit the ability of such holders to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise an insider of the company, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

Other general risks

Unfavorable global economic and geopolitical conditions could adversely affect our business, financial condition, stock price, and results of operations.

Our business could be adversely affected by unstable economic and political conditions within the United States and foreign jurisdictions, including as a result of an economic downturn and geopolitical events, such as changes in U.S. federal policy that affect the geopolitical landscape. Changes to U.S. policy implemented by the U.S. Congress or U.S. presidential administrations have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Since the start of the most recent U.S. presidential administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. For example, the implementation of tariffs by the U.S. government has led to increased trade and political tensions, between not only the U.S. and China, but also between the U.S. and other countries in the international community. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

The global credit and financial markets have also generally experienced extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, fluctuating interest rates, uncertainty about economic stability, global supply chain disruptions, and increases in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflicts between Russia and Ukraine, and in the Middle East, terrorism, political unrest or other geopolitical events. Sanctions imposed by the U.S. and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for our drug candidates and in our ability to raise additional capital when needed on acceptable terms, if at all.

There are also current geopolitical tensions with China that may affect our operations. For example, the recently enacted BIOSECURE Act, which, among other things, prohibits U.S. federal funding in connection with biotechnology equipment or services produced or provided by certain named Chinese "biotechnology companies of concern" and loans and grants to, and federal contracts with any entity that uses biotechnology equipment or services from one of these entities. Any additional executive action, legislative action similar to the BIOSECURE Act or potential sanctions with China could materially impact manufacturing partners and our agreements with them. We continue to assess any legislation as it develops

to determine the effect, if any, on our contractual relationships. Furthermore, any disruptions to our supply chain as a result of unfavorable global economic conditions, including due to geopolitical conflicts, political unrest or public health crises, could negatively impact the timely execution of our ongoing and future clinical trials.

In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent events of political unrest and/or potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

We, or the third parties upon whom we depend, may be adversely affected by natural disasters, public health crises or other business interruptions and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters or public health crises could severely disrupt our operations, and have a material adverse impact on our business, results of operations, financial condition, and prospects. If a natural disaster, power outage, public health crisis or other event occurred that prevented us from conducting our clinical trials, releasing clinical trial results or delaying our ability to obtain regulatory approval for our product candidates, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

We are eligible to be treated as an "emerging growth company" and a "smaller reporting company" and our election of reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). We could be an emerging growth company for up to five years following the completion of our IPO, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, or if we have total annual gross revenue of $1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act");
- providing only two years of audited financial statements in addition to any required unaudited interim financial statements and correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

In addition, the JOBS Act provides that an emerging growth company can also take advantage of an extended transition period for complying with new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. We cannot predict if investors will find our common stock less attractive because we may rely on these

exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

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

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and to implement provisions of the Sarbanes-Oxley Act, impose significant requirements, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Wall Street Reform and Consumer Protection Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have substantially increased, and will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. These increased costs will continue to increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance as a public company, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur as a public company. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be reevaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We have begun the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which requires an annual management assessment of the effectiveness of our internal control over financial reporting. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

For as long as we are an emerging growth company or a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could severely inhibit our ability to accurately report our financial condition and results of operations and could lead to restatements of our financial statements and require us to incur the expense of remediation.

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

We are subject to the periodic reporting requirements of the Exchange Act. Accordingly, we must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

As of December 31, 2025, we had approximately $56.5 million of federal net operating losses ("NOLs"). Federal NOLs generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards in a taxable year is limited to 80% of our taxable income in such year. As of December 31, 2025, we had approximately $2.1 million of state NOLs. Of the state NOLs, some are of indefinite life, but most expire at various dates, beginning in 2040. As of December 31, 2025, we had approximately $7.6 million of federal research and development tax credit carryforwards. Federal tax credit carryforwards expire at various dates, beginning in 2045. As of December 31, 2025, we had approximately $1.0 million of state research and development tax credit carryforwards, which carry forward indefinitely.

Under Sections 382 and 383 of the 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 change (by value) in its equity ownership by "5 percent shareholders" over a three-year period, the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes (including research and development tax credits) to offset its post-change income or taxes may be limited. A corporation that experiences an ownership change will generally be subject to an annual limitation on the use of its pre-ownership change NOLs equal to the value of the corporation immediately before the ownership change, multiplied by the long-term tax-exempt rate (subject to certain adjustments). We may have experienced ownership changes in the past and may experience ownership changes in the future. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs by federal or state taxing authorities or other unforeseen reasons, portions of our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities. As a result, our ability to use our pre-change NOLs and tax credits to offset future taxable income, if any, or taxes could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

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

U.S. federal, state, local and foreign tax laws, regulations and administrative guidance are subject to change as a result of the legislative process and review and interpretation by the U.S. Internal Revenue Service, the U.S. Treasury Department and other taxing authorities. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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

We face an inherent risk of clinical trial and product liability exposure related to the testing of our product candidates in clinical trials, and we will face an even greater risk if we commercially sell any products that we develop. While we currently have no products that have been approved for commercial sale, the ongoing, planned and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others

selling such products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trials;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Although we currently hold clinical trial liability insurance, we will need to obtain and maintain additional insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to obtain and maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

We may become involved in litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

From time to time, we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal data, contractual relations with collaborators and licensors and intellectual property rights. In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, the announcement of negative events, such as negative results from clinical trials, or periods of volatility in the market price of a company's securities. These events may also result in or be concurrent with investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

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

Unregistered Sale of Securities

(a) Set forth below is information regarding securities we have issued within the past three years that were not registered under the Securities Act.

Issuances of Capital Stock

From June 2024 through August 2025, we sold an aggregate of 17,256,508 shares of Series A redeemable convertible preferred stock to accredited investors. 15,711,932 were sold at a purchase price of $19.42 per share, for an aggregate purchase price of approximately $305.2 million while 1,544,576 shares were issued as consideration in connection with certain license agreements at the estimated fair value of $19.10 per share as of issuance date for a total estimated fair value of $29.5 million.

From September 2025 through March 2026, we sold an aggregate of 8,950,199 shares of Series B redeemable convertible preferred stock to accredited investors at a purchase price of $21.37 per share, for an aggregate purchase price of approximately $191.2 million.

From September 2025 through October 2025, we sold an aggregate of 3,780,769 shares of Series B-1 redeemable convertible preferred stock to accredited investors at a purchase price of $21.37 per share, for an aggregate purchase price of approximately $80.8 million.

The offers, sales and issuances of the securities described above were deemed to be exempt under Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D under the Securities Act as a transaction by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business or other relationships, to information about us. No underwriters were involved in these transactions.

Grants and Exercises of Stock Options

Since August, 2023, we have granted to certain of our directors, employees and consultants options to purchase 29,525,329 shares of our common stock at exercise prices ranging from $1.35 to $9.42 per share under the 2023 Plan. Since August 2023, 2,542,452 common stock have been issued upon the exercise of stock options pursuant to the 2023 Plan.

The offers, sales and issuances of the securities described above were deemed to be exempt from registration under Rule 701 promulgated under the Securities Act as transactions under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering. The recipients of such securities were our directors, employees or bona fide consultants and received the securities under our equity incentive plans. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

(b) On June 17, 2026, our Registration Statement on Form S-1, as amended (File No. 333-287125), was declared effective by the Securities and Exchange Commission in connection with our initial public offering. Pursuant to the Registration Statement, we sold an aggregate of 28,750,000 shares of our common stock, including the full exercise by the underwriters of their option to purchase 3,750,000 additional shares, at a public offering price of $16.00 per share. The offering closed on June 22, 2026. J.P. Morgan Securities LLC, Jefferies LLC, Leerink Partners LLC and TD Securities (USA) LLC acted as the underwriters for the offering. The approximate aggregate net proceeds from the initial public offering were $422.4 million, after deducting underwriting discounts and commissions and other offering expenses. The offering terminated upon the sale of all securities registered pursuant to the Registration Statement. No payments for such expenses were made directly or indirectly to (i) any of our directors or executive officers or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates.

There has been no material change in the planned use of proceeds from our initial public offering as described in the final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on June 18, 2026.

(c) None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(a) None.

(b) None.

(c) For the quarterly period covered by this report, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) has adopted, modified, or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Description
2.1+	Agreement and Plan of Merger, by and between the Registrant and Prolaio, Inc., dated as of February 24, 2025, as amended on May 1, 2026 (incorporated herein by reference to Exhibit 2.1 to the Registrant's Registration Statement on Form S-1/A filed on June 11, 2026)
2.2+†	Agreement and Plan of Merger by and among the Registrant, RSF Merger Sub, Inc., Rancho Santa Fe Bio, Inc. and Shareholder Representative Services LLC, as the Representative, dated as of March 11, 2024 (incorporated herein by reference to Exhibit 2.2 to the Registrant's Registration Statement on Form S-1/A filed on June 11, 2026)
3.1	Third Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 23, 2026)
3.2	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on June 23, 2026)
4.1	Specimen Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A filed on June 11, 2026)
4.2	Warrant to Purchase Shares of Common Stock, by and between the Registrant and ARCH Venture Fund XIII, L.P., dated as of September 4, 2025 (incorporated herein by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
4.3	Warrant to Purchase Shares of Common Stock, by and between the Registrant and SCHF (M) PV, L.P., dated as of September 4, 2025 (incorporated herein by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
4.4+	Amended and Restated Investors' Rights Agreement, by and between the Registrant and certain of its stockholders, dated as of September 4, 2025 (incorporated herein by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
10.1#	Kardigan, Inc. 2026 Stock Option and Incentive Plan and form of award agreements thereunder (incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1/A filed on June 11, 2026)
10.2#	Kardigan, Inc. 2026 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1/A filed on June 11, 2026)
10.3#	Form of Indemnification Agreement, by and between the Registrant and its directors and executive officers (incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)

10.4#	Senior Executive Cash Incentive Bonus Plan (incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
10.5#	Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
10.6#	Form of Executive Employment Agreement (incorporated herein by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
10.7#	Bonus Agreement, by and between the Registrant and Tassos Gianakakos dated as of February 24, 2025, as amended by the Bonus Integration Agreement, by and between the Registrant and Tassos Gianakakos, dated September 4, 2025 (incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
10.8#	Bonus Agreement, by and between the Registrant and Jay Edelberg dated as of February 24, 2025, as amended by the Bonus Integration Agreement, by and between the Registrant and Jay Edelberg, dated September 4, 2025 (incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
10.9†	License Agreement, by and between the Registrant and MyoKardia, Inc., dated as of November 4, 2024 (incorporated herein by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
10.10†	License Agreement, by and between the Registrant and Bristol-Myers Squibb Company, dated as of November 4, 2024 (incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
10.11†	License Agreement, between Registrant and Ionis Pharmaceuticals, Inc., effective as of June 7, 2024 (incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
10.12†	License Agreement between Rancho Santa Fe Bio, Inc. and Sanofi, dated June 2, 2021, as amended March 18, 2022, January 9, 2023, and November 7, 2025 (incorporated herein by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
10.13†	Patent License Agreement between Rancho Santa Fe Bio, Inc. and Mayo Foundation for Medical Education and Research, dated December 6, 2019, as amended on May 20, 2021, August 23, 2023, March 10, 2024, June 6, 2024, and December 22, 2025 (incorporated herein by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
10.14†	Agreement and Plan of Merger, by and between the Registrant and Prolaio, Inc., dated as of February 24, 2025, as amended on May 1, 2026 (incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
10.15†	The Cove Lease, by and between the Registrant and HCP Oyster Point III, LLC, dated September 17, 2024 (incorporated herein by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
10.16†	Lease and Lease Agreement by and between Carnegie 506 Associates and the Registrant, dated February 18, 2025 (incorporated herein by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 filed on May 26, 2026)
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

# Indicates a management contract or any compensatory plan, contract or arrangement.

† Certain portions of this document that constitute confidential information have been redacted pursuant to Item 601(b)(10) of Regulation S-K.

+ Certain exhibits and schedules to these agreements have been omitted pursuant to Item 601(a)(5) and (6) of Regulation S-K. The registrant will furnish copies of any of the exhibits and schedules to the Securities and Exchange Commission upon request.

SIGNATURES

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

Kardigan, Inc.

Date: August 11, 2026

By: /s/ Tassos Gianakakos

Tassos Gianakakos
Chief Executive Officer, Director, and Chair
(*Principal Executive Officer*)

Date: August 11, 2026

By: /s/ Brianne Puglisi

Brianne Puglisi
Chief Financial Officer
(*Principal Financial Officer and Principal Accounting Officer*)

Exhibit 31.1

CERTIFICATION 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, Tassos Gianakakos, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kardigan, 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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: August 11, 2026

By: /s/ Tassos Gianakakos
Tassos Gianakakos
Chief Executive Officer, Director, and Chair

Exhibit 31.2

CERTIFICATION 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, Brianne Puglisi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kardigan, 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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: August 11, 2026

By: /s/ Brianne Puglisi
Brianne Puglisi
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Kardigan, Inc. (the "Company") for the period ending June 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 11, 2026

By: /s/ Tassos Gianakakos
Tassos Gianakakos
Chief Executive Officer, Director, and Chair

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Kardigan, Inc. (the "Company") for the period ending June 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 11, 2026

By: /s/ Brianne Puglisi
Brianne Puglisi
Chief Financial Officer