UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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 001-42513

AARDVARK THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**82-1606367**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4370 La Jolla Village Drive, Suite 1050	
San Diego, CA	**92122**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 225-7696

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	**AARD**	**The Nasdaq Stock Market LLC**

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 ☒

The number of shares of Registrant's common stock outstanding as of April 30, 2026 was 21,816,385.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

AARDVARK THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and par value data)

	March 31, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 62,436	$ 47,051
Short-term investments	28,764	62,976
Prepaid expenses and other current assets	2,380	1,859
Total current assets	93,580	111,886
Operating lease right-of-use asset	269	355
Other assets	4,741	4,940
Total assets	$ 98,590	$ 117,181
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,493	$ 2,072
Accrued liabilities	6,775	8,035
Operating lease liability, current portion	336	441
Total current liabilities	11,604	10,548
Total liabilities	11,604	10,548
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized at March 31, 2026 and December 31, 2025; no shares issued and outstanding at March 31, 2026 and December 31, 2025	—	—
Common stock, $0.00001 par value; 490,000,000 shares authorized at March 31, 2026 and December 31, 2025; 21,816,385 and 21,815,353 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	224,478	222,470
Accumulated other comprehensive income	14	81
Accumulated deficit	(137,506)	(115,918)
Total stockholders' equity	86,986	106,633
Total liabilities and stockholders' equity	$ 98,590	$ 117,181

See accompanying notes to unaudited condensed consolidated financial statements.

AARDVARK THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2026	2025
Operating expenses:		
Research and development	$ 16,567	$ 7,755
General and administrative	5,897	2,715
Total operating expenses	22,464	10,470
Loss from operations	(22,464)	(10,470)
Other income (expense), net:		
Unrealized loss on short-term investments	(13)	(15)
Interest and dividend income	889	1,175
Total other income, net	876	1,160
Net loss	$ (21,588)	$ (9,310)
Net loss per share of common stock, basic and diluted (Note 3)	$ (0.99)	$ (0.71)
Weighted-average shares used in net loss per share calculation (Note 3)	21,815,995	13,194,718
Comprehensive income (loss):		
Net loss	$ (21,588)	$ (9,310)
Unrealized (loss) gain on short-term investments	(67)	44
Comprehensive loss	$ (21,655)	$ (9,266)

See accompanying notes to unaudited condensed consolidated financial statements.

AARDVARK THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Outstanding Shares	Amount	Capital	Income	Deficit	Equity
Balance, December 31, 2024	**96,941,453**	**$ 126,756**	**4,066,969**	**$ —**	**$ 3,684**	**$ —**	**$ (58,327)**	**$ (54,643)**
Issuance of common stock in initial public offering, net of discounts and issuance costs of $10.4 million	—	—	6,120,661	—	87,495	—	—	87,495
Conversion of convertible preferred stock into common stock upon initial public offering	(96,941,453)	(126,756)	11,439,838	—	126,756	—	—	126,756
Exercise of common stock options	—	—	57,085	—	101	—	—	101
Vesting of restricted common stock	—	—	3,619	—	13	—	—	13
Stock-based compensation expense	—	—	—	—	233	—	—	233
Unrealized gain on short-term investments	—	—	—	—	—	44	—	44
Net loss	—	—	—	—	—	—	(9,310)	(9,310)
Balance, March 31, 2025	**—**	**$ —**	**21,688,172**	**$ —**	**$ 218,282**	**$ 44**	**$ (67,637)**	**$ 150,689**
Balance, December 31, 2025	**—**	**$ —**	**21,815,353**	**$ —**	**$ 222,470**	**$ 81**	**$ (115,918)**	**$ 106,633**
Exercise of common stock options	—	—	1,032	—	4	—	—	4
Stock-based compensation expense	—	—	—	—	2,004	—	—	2,004
Unrealized loss on short-term investments	—	—	—	—	—	(67)	—	(67)
Net loss	—	—	—	—	—	—	(21,588)	(21,588)
Balance, March 31, 2026	**—**	**$ —**	**21,816,385**	**$ —**	**$ 224,478**	**$ 14**	**$ (137,506)**	**$ 86,986**

See accompanying notes to unaudited condensed consolidated financial statements.

AARDVARK THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Three Months Ended March 31,	
	2026	2025
Operating activities:		
Net loss	$ (21,588)	$ (9,310)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,004	233
Non-cash lease expense	86	107
Unrealized loss on short-term investments	13	15
Amortization of discount on short-term investments	(118)	(81)
Depreciation expense	11	5
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(333)	(4,362)
Accounts payable	2,421	648
Accrued liabilities	(1,260)	1,410
Operating lease liability	(105)	(53)
Net cash used in operating activities	(18,869)	(11,388)
Investing activities:		
Purchases of short-term investments	—	(124,651)
Maturities/sales of short-term investments	34,250	12,027
Net cash provided by (used in) investing activities	34,250	(112,624)
Financing activities:		
Proceeds from sale and issuance of common stock in initial public offering, net of underwriting discounts	—	91,075
Financing costs paid in connection with initial public offering	—	(2,310)
Proceeds from exercises of common stock options	4	110
Net cash provided by financing activities	4	88,875
Net increase (decrease) in cash and cash equivalents	15,385	(35,137)
Cash and cash equivalents at beginning of year	47,051	61,641
Cash and cash equivalents at end of year	$ 62,436	$ 26,504
Supplemental schedule of non-cash financing activity:		
Conversion of convertible preferred stock into common stock upon initial public offering	$ —	$ 126,756

See accompanying notes to unaudited condensed consolidated financial statements.

1. Organization and Basis of Presentation

Description of Business

Aardvark Therapeutics, Inc. ("Aardvark" or the "Company") was incorporated in the State of Delaware on May 17, 2017 and its principal offices are located in San Diego, California. The Company is a clinical-stage biopharmaceutical company focused on developing novel, small-molecule therapeutics to activate innate homeostatic pathways for the treatment of metabolic diseases. The Company targets biological pathways associated with alleviating hunger.

In October 2024, the Company incorporated a wholly-owned subsidiary, Artisan Therapeutics, Inc., in the State of Delaware and contributed certain assets to the new entity. In February 2026, the Company incorporated a wholly-owned subsidiary, Ardia Therapeutics, Inc., in the State of Delaware and contributed certain assets to the new entity.

Principles of Consolidation

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Artisan Therapeutics, Inc. and Ardia Therapeutics, Inc., and have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP"). All intercompany accounts and transactions have been eliminated in consolidation.

Reverse Stock Split

On February 5, 2025, the Company effected a one-for-8.474 reverse stock split of its common stock (the "Reverse Stock Split"). The par value and the authorized shares of the common stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock and the conversion ratio of the redeemable convertible preferred stock have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

Liquidity

As of March 31, 2026, the Company has devoted substantially all of its resources to organizing and staffing the Company, business planning, raising capital, discovering ARD-101, establishing and maintaining its intellectual property portfolio, conducting research, preclinical studies and clinical trials, manufacturing of ARD-101 and related raw materials, and providing general and administrative support for these operations. The Company does not have any products approved for sale and has not generated any revenue to date. In addition, the Company has a limited operating history, has incurred significant net losses and negative cash flows from operations since its inception and expects that its expenses and operating losses will increase substantially for the foreseeable future. As of March 31, 2026, the Company had an accumulated deficit of $137.5 million.

The Company believes its cash, cash equivalents and short-term investments of $91.2 million as of March 31, 2026 will be sufficient for the Company to continue as a going concern for at least one year following the date that the unaudited condensed consolidated financial statements are available to be issued.

The Company will be required to raise additional capital and plans to finance its cash needs through public or private equity or debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, there can be no assurance that the Company will be able to obtain additional funding on acceptable terms, or at all. If the Company is not able to secure adequate additional funding, it may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or delay or reduce the scope of its planned development programs. Any of these actions could materially harm the Company's business, results of operations and future prospects.

Unaudited Condensed Consolidated Interim Financial Information

The unaudited condensed consolidated balance sheet as of March 31, 2026, the unaudited condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2026 and 2025, the unaudited condensed consolidated statements of convertible preferred stock and stockholders' equity for the three months ended March 31, 2026 and 2025, and the unaudited condensed consolidated statements of cash flows for the three months ended March 31, 2026 and 2025 are unaudited. These unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary to present fairly the Company's consolidated financial position, results of operations, and cash flows for the interim period presented.

The financial data and the other financial information contained in these notes to the unaudited condensed consolidated financial statements related to the three months ended March 31, 2026 and 2025 are also unaudited. The consolidated results of operations for the three months ended March 31, 2026 are not necessarily indicative of the results to be expected for the year ending December 31, 2026 or for any other future annual or interim period.

The unaudited condensed consolidated balance sheet as of December 31, 2025 included herein was derived from the audited consolidated financial statements as of that date. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025 filed with the Securities and Exchange Commission on March 23, 2026.

Use of Estimates

The preparation of the Company's unaudited condensed consolidated financial statements requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the unaudited condensed consolidated financial statements and accompanying notes. Such estimates include the estimated incremental borrowing rate for the determination of the Company's operating lease right-of-use assets, valuation of stock-based awards and the accrual of research and development expenses. Management evaluates its estimates on an ongoing basis. Although estimates are based on the Company's historical experience, knowledge of current events, and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash, with original maturities of three months or less when purchased, to be cash equivalents and are stated at cost, which approximates fair value. Cash equivalents are comprised of money market mutual funds and short-term debt obligations of the U.S. Treasury.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts, and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company invests its excess cash in short-term debt obligations of the U.S. Treasury in order to mitigate credit risk and maintain principal and maximize liquidity.

Short-Term Investments

Short-term investments consist of investments in corporate equity securities with readily determinable fair values and short-term debt obligations of the U.S. Treasury with original maturities in excess of three months. The investments in corporate equity securities with readily determinable fair values are reported at fair value with changes in fair value recorded in the unaudited condensed consolidated statements of operations and comprehensive loss. During the three months ended March 31, 2026 and 2025, unrealized losses of $13,000 and $15,000, respectively, were reported in other income (expense), net in the accompanying unaudited condensed consolidated statements of operations and comprehensive loss.

The Company obtains pricing information from its investment manager and generally determines the fair value of debt securities using standard observable inputs, including reported trades, broker/dealer quotes, and bid and/or offers. The Company classifies its investment securities as available-for-sale, as the sale of such securities may be required prior to maturity. Management determines the appropriate classification of its investments in debt securities at the time of purchase. Investments with original maturities beyond three months at the date of purchase and which mature at, or less than 12 months from, the balance sheet date are classified as short-term investments. Investments with contractual maturities beyond one year are also classified as short-term due to the Company's ability to liquidate the investment for use in operations within the next 12 months. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported as accumulated other comprehensive income (loss) until realized. The amortized cost of available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest and dividend income in the accompanying unaudited condensed consolidated statements of operations and comprehensive loss and accrued interest receivable is included in prepaid expenses and other current assets in the accompanying unaudited condensed consolidated balance sheets.

At each balance sheet date, the Company reviews its available-for-sale debt securities that are in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in the unaudited condensed consolidated statements of operations and comprehensive loss. For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through net income (loss). For available-for-sale securities that do not meet the aforementioned criteria, the Company 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, net through an allowance account. There have been no impairment or credit losses recognized during any of the periods presented related to investments in the Company's available-for-sale debt securities.

Fair Value of Financial Instruments

The carrying amounts of cash equivalents, prepaid expenses and other current assets, accounts payable, and accrued expenses are considered to be representative of their respective fair values because of the short-term nature of those instruments.

Research and Development Expenses

Research and development expenses are charged to expense as incurred. Research and development expenses consist primarily of external and internal costs incurred in performing preclinical and clinical development activities. External costs include fees paid to contract research organizations and consultants in connection with product development activities, including regulatory activities, costs related to manufacturing materials for preclinical studies and clinical trials and license fees. Internal costs include personnel-related costs such as salaries and related expenses for employees involved in research and development efforts, facilities-related costs, depreciation, and other allocated expenses. Non refundable advance payments for goods and services for future research and development activities are deferred and included in other assets in the accompanying unaudited condensed consolidated balance sheets and are expensed as the goods are delivered or the related services are performed.

The Company estimates its expenses resulting from its obligations under contracts with vendors, consultants, and contract research organizations in connection with the progress of research and development services performed. The financial terms of these contracts vary from contract to contract and may result in payment flows that do not match the periods over which the services are provided or goods delivered under such contracts. The Company reflects research and development expenses in its unaudited condensed consolidated financial statements by matching those expenses with the period in which services are provided. The Company accounts for these expenses according to the progress of the preclinical or clinical study as measured by the timing of various aspects of the study or the progress of related activities. During the course of a study, the Company reassesses its estimate of performance prospectively based on actual results or any modification to the agreements. Historically, there have been no material differences between the Company's estimates and the amounts actually incurred.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on certain investments. For the three months ended March 31, 2026 and 2025, comprehensive loss includes unrealized gains and losses on short-term investments.

Recent Accounting Standards

From time to time, new accounting standards are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

Recently Issued Accounting Standards Not Yet Adopted

In November 2024, the FASB issued Accounting Standards Update ("ASU") No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40)* ("ASU 2024-03"), which requires new financial statement disclosures in tabular format, in the notes to the unaudited condensed consolidated financial statements, of specified information about certain costs and expenses. This update is effective for all entities beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027. ASU 2024-03 can be applied prospectively or retrospectively and

early adoption is permitted. The Company is currently evaluating the impact of this guidance on its unaudited condensed consolidated financial statements and related disclosures.

3. Net Loss Per Share

Basic net loss per share of common stock attributable to common stockholders is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. The Company has excluded zero and 8,618 weighted-average shares subject to repurchase or forfeiture from the weighted-average number of shares of common stock outstanding for the three months ended March 31, 2026 and 2025, respectively.

Basic and diluted net loss attributable to common holders per share is presented in conformity with the two-class method required for participating securities as the convertible preferred stock were considered participating securities because they participated in dividends with the common stock. The Company also considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of all series of convertible preferred stock and the holders of early exercised shares subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share for those periods. Accordingly, for the three months ended March 31, 2026 and 2025, there is no difference in the number of shares used to calculate basic and diluted shares outstanding.

The Company excluded the following potential shares of its common stock, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	March 31,	
	2026	2025
Options to purchase common stock	3,829,482	1,123,545
Common stock subject to repurchase rights	—	7,748
Employee Stock Purchase Plan shares	62,692	—
Total	3,892,174	1,131,293

4. Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

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

Level 2—Observable inputs, such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

As of March 31, 2026 and December 31, 2025, assets measured at fair value on a recurring basis were as follows (in thousands):

	March 31, 2026			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents				
Money market mutual funds	$ 52,404	$ 52,404	$ —	$ —
Total cash equivalents	$ 52,404	$ 52,404	$ —	$ —
Short-term investments				
Scilex Holding Company common stock	$ 17	$ 17	$ —	$ —
Sorrento Therapeutics, Inc. common stock	2	2	—	—
U.S. Treasury obligations	28,745	—	28,745	—
Total short-term investments	$ 28,764	$ 19	$ 28,745	$ —

	December 31, 2025			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents				
Money market funds	$ 29,379	$ 29,379	$ —	$ —
U.S. Treasury obligations	4,999	—	4,999	—
Total cash equivalents	$ 34,378	$ 29,379	$ 4,999	$ —
Short-term investments				
Scilex Holding Company common stock	$ 30	$ 30	$ —	$ —
Sorrento Therapeutics, Inc. common stock	2	2	—	—
U.S. Treasury obligations	62,944	—	62,944	—
Total short-term investments	$ 62,976	$ 32	$ 62,944	$ —

There were no transfers in or out of Level 3 during the three months ended March 31, 2026 and 2025.

The Company determines the fair value of its money market mutual funds and treasury bonds based upon quoted prices in active markets for identical and similar assets as applicable. At March 31, 2026 and December 31, 2025, the Company did not hold any investments, within cash equivalents, that were in a material unrealized gain or loss position.

5. Short-Term Investments

The following tables summarize the available-for-sale investment debt securities held at March 31, 2026 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury obligations	$ 28,731	$ 14	$ —	$ 28,745
Total	$ 28,731	$ 14	$ —	$ 28,745

The following table summarizes the available-for-sale debt investment securities held at December 31, 2025 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury obligations	$ 62,863	$ 81	$ —	$ 62,944
Total	$ 62,863	$ 81	$ —	$ 62,944

As of March 31, 2026, the available-for-sale investment debt securities by contractual maturity were as follows (in thousands):

	Amortized Cost	Fair Value
Due in one year or less	$ 28,731	$ 28,745
Total	$ 28,731	$ 28,745

6. Balance Sheet Details

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2026	December 31, 2025
Research and development costs	$ 4,502	$ 4,700
Compensation-related expenses	1,518	2,913
Other	755	422
Total accrued liabilities	$ 6,775	$ 8,035

7. Stockholders' Equity

Initial Public Offering and Related Transactions

In February 2025, the Company completed its initial public offering ("IPO") with the sale of 6,120,661 shares of common stock at an initial public offering price of $16.00 per share, which included the partial exercise by the underwriters of their option to purchase 232,661 additional shares, which resulted in net proceeds to the Company of approximately $87.5 million, after deducting underwriting discounts and commissions of approximately $6.9 million and offering-related transaction costs of approximately $3.5 million.

In addition, in connection with the completion of the IPO on February 14, 2025, all outstanding shares of convertible preferred stock were converted into 11,439,838 shares of the Company's common stock and the Company's certificate of incorporation was amended and restated to authorize 490,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock.

ATM Facility

In March 2026, the Company entered into an Equity Distribution Agreement with Piper Sandler & Co. (the "Agent"), pursuant to which the Company may, from time to time, offer and sell through the Agent shares (the "Shares") of its common stock (the "ATM Facility"). The issuance and sale of the Shares, if any, will be made pursuant to the Company's shelf registration statement on Form S-3 (Registration Statement No. 333-294537), filed with the Securities and Exchange Commission on March 23, 2026, including the equity distribution agreement prospectus (the "Equity Distribution Agreement Prospectus") contained therein. Pursuant to the Equity Distribution Agreement Prospectus, the Company may offer and sell Shares having an aggregate offering price of up to $150.0 million. The Equity Distribution Agreement provides that the Company will pay the Agent a commission at a rate of 3.0% of the gross sales price per Share sold under the Equity Distribution Agreement. The Company has no obligation to sell any Shares under the Equity Distribution Agreement. As of March 31, 2026, no shares of common stock have been sold under the ATM Facility.

Equity Incentive Plans

In December 2024, the Company's board of directors adopted the 2025 Equity Incentive Plan (the "2025 Plan"), and the Company's stockholders approved the 2025 Plan in February 2025. The 2025 Plan, pursuant to which 2,150,000 shares were initially reserved for issuance, became effective on February 11, 2025. Upon the effectiveness of the 2025 Plan, no further grants will be made under the 2017 Stock Plan (as amended, the "Plan"). In May 2025, the Company adopted the 2025 Inducement Equity Incentive Plan (the "2025 Inducement Plan", and collectively with the 2025 Plan and the Plan, referred to as the "Plans") pursuant to which an additional 900,000 shares of common stock were reserved to be used exclusively for the grant of equity awards as a material inducement for individuals to commence employment with the Company in compliance with Nasdaq Listing Rule 5635(c)(4).

The maximum term of the options granted under the Plans is no more than ten years. Grants 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. The Plans allow for the early exercise of all stock options granted if authorized by the 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.

Stock-Based Compensation Expense

The allocation of stock-based compensation expense was as follows (in thousands):

	Three Months Ended March 31,	
	2026	2025
Research and development expense	$ 792	$ 160
General and administrative expense	1,212	73
Total stock-based compensation expense	$ 2,004	$ 233

As of March 31, 2026, the unrecognized compensation cost related to outstanding time-based options was $25.9 million and is expected to be recognized over a weighted-average period of 3.2 years.

Employee Stock Purchase Plan

In January 2025, the Company's board of directors adopted the 2025 Employee Stock Purchase Plan (the "ESPP"), which became effective on February 11, 2025. The ESPP permits participants to purchase common stock through payroll deductions of up to 100% of their eligible compensation. Initially, a total of 215,000 shares of common stock was reserved for issuance under the ESPP. The first offering period under the ESPP commenced in April 2025. Stock compensation expense for the three months ended March 31, 2026 related to the ESPP was immaterial. As of March 31, 2026, the unrecognized compensation cost related to current offering periods under the ESPP was $0.7 million and is expected to be recognized over a weighted-average period of 1.0 year.

8. Commitments and Contingencies

Acquisition-Related Liabilities

The Company has previously acquired the rights to certain intellectual property in exchange for upfront cash payments and the sellers' right to receive additional consideration upon the achievement of specified regulatory and commercial milestones associated with products developed by the Company utilizing the acquired in-process research and development. At March 31, 2026, potential future regulatory and commercial milestone payments under these agreements totaled an aggregate of approximately $180.5 million.

Contingencies

From time to time, the Company may become subject to claims or suits arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. As of March 31, 2026, the Company's management is not aware of any legal proceedings or matters that could have a material adverse effect on the Company's financial position, results of operations or cash flows.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with officers and members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. At March 31, 2026, no claims exist under indemnification arrangements and accordingly, no amounts have been accrued in its unaudited condensed consolidated financial statements as of March 31, 2026.

9. Related Party Transactions

The Company's Chief Executive Officer is a member of the board of directors of Aardwolf Therapeutics, Inc. (Note 10).

10. Aardwolf Spinoff

In May 2022, through a series of transactions, the Company spun off certain assets of the Company (the "Spinoff") to Aardwolf Therapeutics, Inc. ("Aardwolf"). In accordance with authoritative guidance, the Company has determined that it holds a variable

interest in Aardwolf and Aardwolf meets the definition of a variable interest entity ("VIE") as Aardwolf does not have the ability to finance its activities without additional subordinated financial support and its equity investors will not absorb their proportionate share of expected losses. However, as the Company does not have both (i) the power to direct the economically significant activities of Aardwolf and (ii) the obligation to absorb losses of, or the right to receive benefits from, Aardwolf, the Company is not considered the primary beneficiary of Aardwolf and has not consolidated the financial position or results of operations of Aardwolf in the accompanying unaudited condensed consolidated financial statements, although Aardwolf is considered a related party of the Company. The Company will continuously perform this assessment, as changes to existing relationships or future transactions may result in the consolidation or deconsolidation of a VIE. At March 31, 2026 and December 31, 2025, the maximum exposure to loss was zero.

11. Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group ("CODM"), in making decisions regarding resource allocation and assessing performance. The Company's CODM is its Chief Executive Officer. No product revenue has been generated since inception and all assets are held in the United States.

The Company views its operations and manages its business as one operating segment, focused on the discovery and development of novel therapies for the treatment of metabolic diseases. Segment profit or loss is measured as the Company's net loss as reported on the Company's unaudited condensed consolidated statements of operations and comprehensive loss. The Company monitors its cash and cash equivalents and short-term investments as reported on the Company's unaudited condensed consolidated balance sheets to determine funding for its research and development. The measure of segment assets is reported on the condensed consolidated balance sheet as total assets.

As the Company does not currently generate revenue, the CODM assesses Company performance through the achievement of pre-clinical and clinical research goals. In addition to the Company's unaudited condensed consolidated statements of operations and comprehensive loss, the CODM is regularly provided with budgeted and forecasted expense information which is used to determine the Company's liquidity needs and cash allocation.

Segment net loss, including significant segment expenses regularly provided to the CODM, are as follows (in thousands):

	Three Months Ended March 31,	
	2026	2025
Research and development expenses:		
Research expenses	$ 12,628	$ 5,496
Personnel-related (including stock-based compensation expense)	3,709	2,057
Facilities-related and other allocated costs	230	202
Total Research and development expenses	16,567	7,755
General and administrative expenses	5,897	2,715
Interest and dividend income	(889)	(1,175)
Unrealized losses on short-term investments	13	15
Net loss	$ 21,588	$ 9,310

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q (Quarterly Report). This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risk, assumptions and uncertainties, such as statements of our plans, objectives, expectations, intentions, forecasts and projections. Our actual results and the timing of selected events could differ materially from those discussed in these forward-looking statements as a result of several factors, including those set forth under Part II, Item 1A, "Risk Factors", of this Quarterly Report and elsewhere in this Quarterly Report. You should carefully read Part II, Item 1A, "Risk Factors", of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements" below.

Special Note Regarding Forward-Looking Statements

This Quarterly Report contains forward-looking statements about us and our industry within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), and Section 27A of the Securities Act of 1933, as amended (the Securities Act), which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of preclinical studies and clinical trials, research and development plans and costs, plans for manufacturing, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "might," "should," "would," "expects," "plans," "anticipates," "could," "intends," "target," "outlook," "projects," "forecast," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about:

- the initiation, timing, progress, status and results of our preclinical studies, clinical trials and research and development programs for our product candidates, and our anticipated timeline for providing further guidance on, or results of, our preclinical studies and clinical trials;
- our ability to demonstrate, and the timing of, preclinical proof-of-concept in vivo for our product candidates;
- our ability to successfully restart or complete our clinical trials;
- our ability to quickly leverage our initial product candidates and to progress additional candidates;
- the prevalence of certain diseases and conditions we intend to treat and the size of the market opportunity for our product candidates;
- estimates of the number of patients with certain diseases and conditions we intend to treat and the number of subjects that we intend to enroll in our clinical trials;
- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates;
- the beneficial characteristics, including safety, efficacy and therapeutic effects, and potential advantages of our product candidates;
- the timing or likelihood of regulatory filings and approval for our product candidates;
- our ability to meet future regulatory standards with respect to our product candidates, if approved;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications that we may pursue;
- our ability to identify additional product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the rate and degree of market acceptance and therapeutic benefits of our product candidates, if approved, and any other product candidates we may develop;
- the implementation of our strategic plans for our business, product candidates, research programs and technologies;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;

- anticipated developments related to our competitors and our industry;
- our competitive position and ability to leverage the clinical, regulatory and manufacturing advancements to accelerate our clinical trials and regulatory approval of product candidates;
- the success of competing therapies that are or may become available;
- our ability to identify and enter into future license agreements and collaborations;
- the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory, manufacturing or commercialization expertise;
- our ability to efficiently and cost-effectively conduct our current and future clinical trials;
- our reliance on third parties to conduct clinical trials of our product candidates;
- our reliance on third parties for the manufacture of our product candidates;
- our plans relating to sales strategy, manufacturing and commercializing our product candidates, if approved;
- our ability to attract and retain sales personnel, or to contract with a sales organization, if our product candidates are approved;
- anticipated regulatory and legal developments in the United States and foreign countries in which we may seek regulatory approval for our product candidates in the future;
- our ability to expand internationally;
- our ability to attract and retain key scientific and management personnel;
- our expected or anticipated financial performance;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates, if approved;
- our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements, including our ability to comply with our financial obligations pursuant to the terms of such agreements;
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act or a smaller reporting company; and
- our anticipated use of our cash, cash equivalents and short-term investments resources, estimates of our expenses, capital requirements and needs for additional financing.

We caution you that the forward-looking statements highlighted above do not encompass all of the forward-looking statements made in this Quarterly Report.

We have based the forward-looking statements contained in this Quarterly Report primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations or growth prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in Part II, Item 1A,“Risk Factors”, of this Quarterly Report and this Part I, Item 2, “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, of this Quarterly Report and elsewhere in this Quarterly Report. Moreover, we operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission (SEC) after the date of this Quarterly Report.

In addition, statements that “we believe” and similarly qualified statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should

not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to rely unduly upon them.

The forward-looking statements made in this Quarterly Report relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report to reflect events or circumstances after the date of this Quarterly Report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, other strategic transactions or investments we may make or enter into.

Throughout this Quarterly Report, unless the context otherwise requires, the terms "Aardvark," "we," "us" and "our" in this Quarterly Report refer to Aardvark Therapeutics, Inc. and its subsidiaries.

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel, small-molecule therapeutics to activate innate homeostatic pathways for the treatment of metabolic diseases. We target biological pathways associated with alleviating hunger that we believe have the potential to deliver transformative outcomes for patients. We have focused our efforts on developing selective compounds, targeting Bitter Taste Receptors (TAS2Rs) for hunger-associated conditions. Our initial compounds target TAS2Rs at the luminal surface of the gut epithelium, which normally respond to the chemicals in food and participate in the gut-brain axis. Our research has shown that activating these receptors can induce the secretion of endogenous signaling molecules, including cholecystokinin (CCK), peptide YY (PYY) and glucagon-like peptide-1 (GLP-1).

TAS2Rs are a family of 26 different nutrient-sensing G protein-coupled receptors (GPCRs) that are broadly expressed among vertebrates. TAS2Rs are present in the oral cavity to convey bitter taste and are highly expressed in many other tissues throughout the body where they are key in regulating metabolic and inflammatory pathways. CCK has long been recognized as a promising pharmaceutical target because its release is triggered with food and it helps suppress hunger, which is the feeling of discomfort that comes from a perception of not having eaten recently. We believe suppression of hunger could be complementary to the suppression of appetite reported from patients on GLP-1 receptor targeted treatments, which reduce the desirability of food. Previous approaches to directly agonize CCK receptors through exogenous molecules have been limited by safety concerns driven by systemic exposure, resulting in on-target activity in undesired tissues and have been associated with pancreatic safety concerns, including pancreatitis. Our wholly-owned lead product candidate, ARD-101, is an oral, largely gut-restricted small-molecule agonist of certain TAS2Rs expressed on luminally accessible enteroendocrine cells lining the gut. ARD-101, in contrast to previous approaches to directly agonize CCK receptors, elicits the endogenous release of CCK by leveraging the body's natural response to TAS2R agonism. To our knowledge, besides our product candidates, there are no approved therapies and no other clinical-stage candidates that directly target TAS2Rs.

ARD-101 has limited systemic absorption, which we believe reduces the potential for systemic toxicity and has contributed to ARD-101 being well-tolerated in our Phase 1 and 2 trials. We have completed a Phase 1 clinical trial of ARD-101 in healthy volunteers and a Phase 2 clinical trial in subjects with hyperphagia associated with Prader-Willi Syndrome (PWS). The Phase 2 clinical trial in hyperphagia associated with PWS evaluated two dosing regimens over 28 days followed by a 14-day withdrawal period. In Part 1 of the trial, 12 subjects completed the treatment period at a fixed dose of 200 mg delivered orally twice daily (BID). These 12 subjects that completed treatment had no significant treatment-related adverse events and, of these subjects, eight completed the Hyperphagia for Clinical Trial Questionnaire-9 (HQ-CT 9), with seven having complete post–database lock datasets. In this subgroup of seven, the mean decline at day 28 was approximately 9 points. In Part 2 of the trial, four subjects were dosed under a revised protocol: 400 mg BID for seven days, followed by 600 mg BID for seven days and ending with 800 mg BID for 14 days. The four subjects that completed the trial per protocol had only grade 1 treatment-related adverse events and showed a decrease in HQ-CT 9 of approximately eight points at 28 days. Thus, in our completed Phase 2 clinical trial in subjects with hyperphagia associated with PWS, ARD-101 was shown to be well-tolerated and demonstrated clinical activity through a reduction in Hyperphagia Questionnaire for Clinical Trials (HQ-CT) scores.

In the second quarter of 2025, we initiated dosing for a Phase 3 clinical trial for hyperphagia associated with PWS, which we refer to as the HERO (**H**unger **E**limination or **R**eduction **O**bjective) trial. We previously reached alignment with the FDA on a protocol for a Phase 3 clinical trial, which we initiated in December 2024. In August 2025, we submitted a protocol amendment to remove the use of anti-psychotics and insulin-requiring type 2 diabetes as exclusion criteria for the clinical trial. In October 2025, we reached alignment with the FDA on a protocol amendment to lower the minimum age of eligibility to participate in the trial from 13 to 10 years of age. This change broadened the eligible trial population and expanded the potential addressable opportunity within PWS. In December 2025, we submitted an additional protocol amendment seeking to further lower the minimum age of eligibility to participate in the trial to 7 years of age. During the third quarter of 2025, we commenced enrollment for the HERO Open Label Extension (OLE) trial, which was available to patients completing the HERO trial and we initiated our first clinical sites in Australia. In January 2026, we announced over 50% completion of the target enrollment of 90 patients in the HERO trial and within the first quarter of 2026, we initiated clinical sites in the UK, South Korea and Canada.

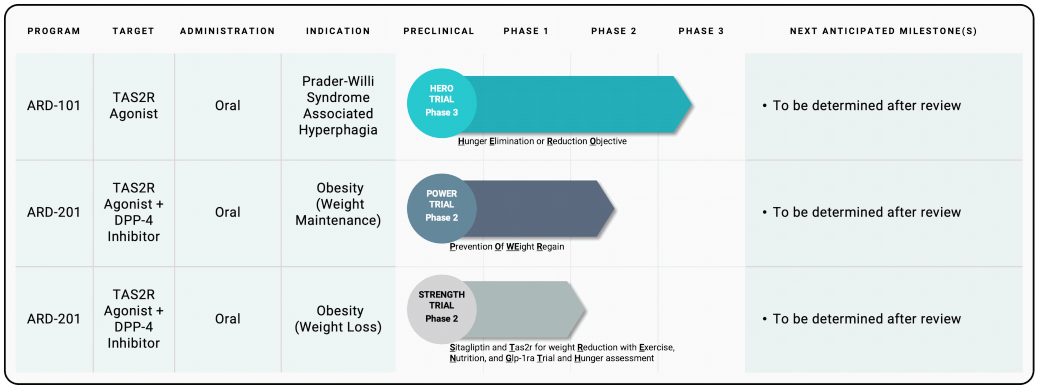
On February 27, 2026, we voluntarily paused enrollment and dosing in the HERO and OLE trials following reversible cardiac observations in a healthy volunteer study and are currently reviewing the data and collaborating with the FDA to determine next steps. As a result, aspects of the trial design, development timeline and future clinical plans may change. Following the voluntary pause, we are reviewing the trial designs and protocols in collaboration with the FDA and the previously agreed protocol elements may be revisited.

Our second TAS2R program, ARD-201, was planned to be a fixed-dose combination of ARD-101 and a dipeptidyl peptidase-4 (DPP-4) inhibitor for the treatment of obesity and obesity-related conditions, including the prevention of weight regain following treatment with GLP-1 receptor agonists, which we believe may address an important unmet need in the long-term management of obesity. We previously initiated a Phase 2 clinical trial, which we referred to as the POWER (**P**revention **O**f **WE**ight **R**egain) trial, in December 2025, to explore the efficacy of ARD-201 in the prevention of weight regain among patients who have successfully lost over 15% of body weight on GLP-1RA therapy. In addition, we previously planned to initiate a second Phase 2 trial for ARD-201 in the first half of 2026, which we referred to as the STRENGTH (**S**itagliptin and **T**AS2R for weight **R**eduction with **E**xercise, **N**utrition, and GLP-1RA **T**rial and **H**unger assessment) trial. Because ARD-201 contains ARD-101 as a component of the planned combination therapy, we are assessing the potential implications of the voluntary pause of the HERO trial on the ARD-201 program, including the potential impact of the safety observations identified in the healthy volunteer study in the ARD-101 program on the development of ARD-201. Following this assessment, we have voluntarily paused the STRENGTH and POWER clinical trials, in addition to the HERO and OLE trials (collectively, the "voluntarily paused clinical programs"), while we complete our ongoing evaluation of the safety observations identified in the healthy volunteer study of ARD-101 and continue discussions with the FDA regarding next steps for the ARD-101 program. We expect to provide further guidance in the second quarter of 2026.

In preparation for these trials, we expanded our clinical management and regulatory capabilities, including hiring clinical, regulatory, CMC and quality personnel, and we expect to continue to need to expand our clinical management and regulatory capabilities and to rely on third parties to conduct our later stage or pivotal clinical trials in the future. However, the timing of additional staffing and operational expansion may be delayed as we evaluate next steps following the voluntary pause of our clinical programs, although we expect to continue to build our capabilities over time as our clinical programs progress, subject to the outcome of our ongoing review and discussions with the FDA.

Below is a summary of our portfolio of wholly-owned novel and proprietary small-molecule programs that we believe can induce satiety in patients with hunger-associated indications. As discussed above, certain clinical programs, including the HERO trial for ARD-101 and the POWER and STRENGTH trials for ARD-201, are currently paused while we evaluate safety observations and continue discussions with the FDA regarding next steps.

Our Hunger Associated TAS2R Pipeline



Beyond our lead product candidate, ARD-101, we are also developing other programs for the potential treatment of indications with high unmet need, including other indications mediated by TAS2R signaling.

Since we commenced operations in 2017, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, discovering ARD-101, establishing and maintaining our intellectual property portfolio, conducting research, preclinical studies, and clinical trials, manufacturing of ARD-101 and related raw materials, and providing general and administrative support for these operations.

We have incurred significant net losses and negative cash flows from operations since our inception and, as of March 31, 2026, we had an accumulated deficit of $137.5 million. Our net losses for the three months ended March 31, 2026 and 2025 were $21.6 million and $9.3 million, respectively. We expect our expenses and operating losses will increase substantially for the foreseeable future as we:

- continue our development of ARD-101 and evaluate next steps following the voluntary pause of our clinical programs;
- seek to discover and develop additional product candidates;
- conduct our ongoing and planned clinical trials and preclinical studies;
- continue our research and development activities;
- utilize third parties to manufacture ARD-101 and our other product candidates and related raw materials;
- hire additional personnel as our clinical programs advance and as we determine next steps following the voluntary pause of our clinical programs;
- maintain, expand and protect our intellectual property;
- implement operational, financial and management information systems; and
- potentially experience any delays, challenges, or other issues associated with the clinical development of our product candidates, including with respect to our regulatory strategies.

If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of and level of expense related to our clinical trials and preclinical studies and our other research and development activities and capital expenditures and the timing and amount of any milestone or royalty payments due under our existing or future license or collaboration agreements.

From inception and up to the date of our initial public offering (IPO) in February 2025, we had raised a total of $129.1 million in gross proceeds to fund our operations from the sale and issuance of shares of our convertible preferred stock. In February 2025, we completed our IPO with the sale of 6,120,661 shares of common stock, which included the partial exercise by the underwriters of their option to purchase 232,661 additional shares, at an IPO price of $16.00 per share and received net proceeds of approximately $87.5 million. As of March 31, 2026, we had cash, cash equivalents and short-term investments of $91.2 million. Based upon our current operating plans, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our projected operations into mid-2027. However, our forecast of 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. In February 2026, we voluntarily paused enrollment and dosing in the Phase 3 HERO trial and the open label extension trial for ARD-101, and the POWER and STRENGTH clinical trials for ARD-201 based on reversible cardiac observations in a healthy volunteer study of ARD-101. The voluntary pause of these clinical trials may affect the timing and amount of our future expenditures and our need for additional capital, depending on the outcome of our ongoing data review and discussions with the FDA regarding next steps for our clinical programs.

We do not have any products approved for sale and have not generated any revenue to date. We do not expect to generate any revenue from product sales until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years and may never occur. We will need substantial additional funding in addition to the net proceeds of our IPO to support our continuing operations and pursue our long-term business plan, including to complete the development and commercialization of ARD-101 and our other product candidates, if approved. Accordingly, until such time as we can generate significant revenue from sales of ARD-101 or our other 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. 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 research and development programs or other operations, or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our ARD-101 and our other product candidates for preclinical and clinical testing, as well as for commercial manufacture if ARD-101 or any of our other product candidates obtain marketing approval. We are working with our current manufacturers to ensure that we will be able to scale up our manufacturing capabilities to support our clinical plans. In addition, we rely on third parties to package, label, store, and distribute ARD-101, and we intend to rely on third parties for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the discovery and development of ARD-101 and our other product candidates.

We have appointed a Chief Commercial Officer; however, given our stage of development, we have not yet built out a marketing or sales organization or commercial infrastructure. We intend to build the necessary sales, marketing and commercialization capabilities and infrastructure over time as our product candidates advance through clinical development if and when our product candidates advance through clinical development and receive regulatory approval. We expect to spend a significant amount in commercial development and marketing costs prior to obtaining regulatory and marketing approval of one or more of our product candidates.

Macroeconomic Trends

We may be affected by unfavorable economic conditions and challenges in the United States and abroad, such as the effects of the ongoing conflicts in the Middle East, including the war in Iran and its surrounding regions, and between Russia and Ukraine, sanctions against Russia, the instability in Venezuela, disruptions in the banking industry and inflationary trends. The fiscal years 2025 and 2024 were marked by significant market uncertainty and increasing inflationary pressures. These market dynamics are expected to continue in 2026, and these and similar adverse market conditions may negatively impact our business, financial position, results of operations and growth prospects. For further discussion of the potential impacts of macroeconomic events on us, refer to Part II, Item 1A, “Risk Factors”, of this Quarterly Report.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from the sale of products. We do not expect to generate any such revenue unless and until such time as ARD-101 and our other product candidates have advanced through clinical development and regulatory approval, if ever. If we fail to complete preclinical and clinical development of any 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

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Our research and development (R&D) expenses consist primarily of external and internal costs incurred in performing preclinical and clinical development activities. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Our research and development expenses consist principally of:

- external costs, including:
- fees paid to CROs and consultants in connection with our preclinical studies, toxicology and clinical trials;
- costs related to manufacturing materials for our preclinical studies and clinical trials;
- costs related to compliance with regulatory requirements;
- license fees; and
- internal costs, including:
- personnel-related costs such as salaries, bonuses, payroll taxes, employee benefits, travel, and stock-based compensation expense for employees involved in research and development efforts; and

- facilities-related costs, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, insurance, equipment, and other supplies and services.

We do not track our research and development expenses on a program-specific basis or allocate our internal costs associated with our discovery and development efforts because these costs are deployed across multiple programs and, as such, are not separately classified. Since our inception and through March 31, 2026, substantially all of our external costs have been related to the research and development of ARD-101.

Although R&D activities are central to our business model, the successful development of ARD-101 and our other product candidates is highly uncertain. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of ARD-101 or any other current or future product candidates due to the inherently unpredictable nature of preclinical and clinical development. There are numerous factors associated with the successful development of a product candidate, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our clinical development programs. Product candidates in later stages of development generally have higher development costs than those in earlier stages of development. As a result, we expect that our R&D expenses will increase substantially for the foreseeable future as we continue to conduct our ongoing R&D activities, advance preclinical research programs toward clinical development, conduct clinical trials, hire additional personnel, and maintain, expand, protect, and enforce our intellectual property portfolio.

At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. Our future R&D expenses may vary significantly based on a wide variety of factors such as:

- the number and scope, rate of progress, expense and results of our discovery and preclinical activities and clinical trials;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the extent of changes in government regulation and regulatory guidance;
- the efficacy and safety profile of our product candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities; and
- the extent to which we establish collaboration, license, or other arrangements.

A change in the outcome of any of these variables with respect to development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for ARD-101 or any other current or future product candidates may be affected by a variety of factors. We may never succeed in achieving regulatory approval for any of our product candidates. Preclinical and clinical development timelines, the probability of success, and total development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate

on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments, and our ongoing assessments as to each product candidates' commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidate may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

General and Administrative

Our general and administrative (G&A) expenses consist primarily of personnel-related costs such as salaries, bonuses, payroll taxes, employee benefits, travel, and stock-based compensation expense for employees involved in executive, accounting and finance, legal, and other administrative functions. Other significant costs include allocated facility-related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services, insurance costs, and business development expenses.

We expect that our G&A expenses will increase substantially for the foreseeable future as we continue to increase our general and administrative headcount to support our continued R&D activities and, if ARD-101 or our other product candidates receive marketing approval, commercialization activities, as well as to support our operations generally, although the timing of additional hiring may depend on the outcome of our evaluation of the voluntarily paused clinical programs.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on our invested cash and cash equivalents, dividend income and changes in the fair value of equity securities held as investments.

Results of Operations

Comparison of the Three Months ended March 31, 2026 and 2025

The following table summarizes our results of operations for each of the periods indicated:

	Three Months Ended March 31,		
	2026	2025	Change
(in thousands)			
Operating expenses:			
Research and development	$ 16,567	$ 7,755	$ 8,812
General and administrative	5,897	2,715	3,182
Total operating expenses	22,464	10,470	11,994
Loss from operations	(22,464)	(10,470)	(11,994)
Other income, net	876	1,160	(284)
Net loss	$ (21,588)	$ (9,310)	$ (12,278)

Research and Development Expenses

The following table summarizes our R&D expenses for each of the periods indicated:

	Three Months Ended March 31,		
(in thousands)	2026	2025	Change
External costs	$ 12,628	$ 5,496	$ 7,132
Internal costs:			
Personnel-related (including stock-based compensation expense)	3,709	2,057	1,652
Facilities-related (including depreciation) and other allocated costs	230	202	28
Total internal costs	3,939	2,259	1,680
Total R&D expenses	$ 16,567	$ 7,755	$ 8,812

R&D expenses were $16.6 million and $7.8 million for the three months ended March 31, 2026 and 2025, respectively. The $8.8 million increase for the three months ended March 31, 2026 as compared to the three months ended March 31, 2025 resulted primarily from an increase of $7.1 million for external expenses incurred for chemistry, manufacturing and controls (CMC), clinical and toxicology studies primarily related to the development of ARD-101 and a $1.7 million increase in personnel-related costs due to increased headcount and bonuses.

General and Administrative (G&A) Expenses

G&A expenses were $5.9 million and $2.7 million for the three months ended March 31, 2026 and 2025, respectively. The $3.2 million increase for the three months ended March 31, 2026 as compared to the three months ended March 31, 2025 resulted primarily from a $2.1 million increase in personnel-related costs due to increased headcount and bonuses, a $0.6 million increase in legal and other professional costs, and a $0.3 million increase in facilities and other costs. The increase in non-facilities costs were partially related to commencing operations as a public company in February 2025.

Other Income, Net

Other income, net was $0.9 million and $1.2 million for the three months ended March 31, 2026 and 2025, respectively. The $0.3 million decrease for the three months ended March 31, 2026 as compared to the three months ended March 31, 2025 resulted from lower interest income generated by our lower invested cash balances.

Liquidity and Capital Resources

Sources of Liquidity

We have not generated any revenue from product sales and have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. From inception and up to the date of our IPO in February 2025, we had raised a total of $129.1 million in gross proceeds to fund our operations from the sale and issuance of shares of our convertible preferred stock. In February 2025, we completed our IPO with the sale of 6,120,661 shares of common stock, which included the partial exercise by the underwriters of their option to purchase 232,661 additional shares, at an IPO price of $16.00 per share and received net proceeds of $87.5 million.

We currently have an effective shelf Registration Statement on Form S-3 (File No. 333-294537) that became effective on April 3, 2026, which allows us to undertake various equity and debt offerings up to $400.0 million. In addition, on March 23, 2026, we entered into an Equity Distribution Agreement with Piper Sandler & Co. (the Agent), pursuant to which we may offer and sell from time to time through the Agent up to $150.0 million in shares of our common stock (the ATM Facility). We are not obligated to sell any shares under the Equity Distribution Agreement, and the Agent is not obligated to buy or sell any shares of our common stock. We cannot provide any assurance that we will sell any shares under the Equity Distribution Agreement, or, if we do, as to the prices, amounts, or timing of any such sales. As of March 31, 2026, we have not sold any shares of common stock under the ATM Facility.

Future Funding Requirements

As of March 31, 2026, we had cash, cash equivalents and short-term investments of $91.2 million. Based upon our current operating plans, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our projected operations into mid-2027. However, our forecast of 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. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of conducting preclinical studies, manufacturing and testing product candidates in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain. In February 2026, we voluntarily paused enrollment and dosing in our Phase 3 HERO trial and the open label extension trial for ARD-101, and the POWER and STRENGTH clinical trials for ARD-201. The voluntary pause of these clinical trials may affect the timing and amount of our future expenditures and our need for additional capital, depending on the outcome of our ongoing data review and discussions with the FDA regarding next steps for our voluntarily paused clinical programs.

We have incurred significant operating losses since our inception and, as of March 31, 2026, we had an accumulated deficit of $137.5 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially for the reasons described above.

Our future capital requirements are difficult to predict and depend on many factors, including but not limited to:

- the initiation, type, number, scope, progress, expansions, results, costs, and timing of clinical trials and preclinical studies of our current and future product candidates, including the costs of any third-party products used as combination agents in our combination clinical trials;
- the costs and timing of manufacturing for our product candidates, including commercial manufacture at sufficient scale, if any product candidate is approved;
- the costs, timing, and outcome of regulatory meetings and reviews of our product candidates;
- the costs of obtaining, maintaining, enforcing, and protecting our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting;
- the costs associated with hiring additional personnel and consultants as our clinical and preclinical activities increase;
- the timing and payment of milestone, royalty or other payments we must make pursuant to our existing and potential future license or collaboration agreements with third parties;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidates 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;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses, and other similar arrangements;
- costs associated with any products or technologies that we may in-license or acquire; and
- the effects of competing technological and market developments as well as disruptions to and volatility in the credit and financial markets.

We have no other committed sources of capital. Until we can generate a sufficient amount of product revenue to finance our cash requirements, if ever, we expect to finance our future cash needs primarily through equity offerings, debt financings, or other capital sources, including potential 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, 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 additional funds through other collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, product candidates, research programs, intellectual property or proprietary technology, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce, or terminate our R&D programs or other operations, or grant rights to develop and market our product candidates to third parties that we would otherwise prefer to develop and market ourselves, or on less favorable terms than we would otherwise choose.

Cash Flows

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

	Three Months Ended March 31,	
	2026	2025
(in thousands)		
Net cash used in operating activities	$ (18,869)	$ (11,388)
Net cash provided by (used in) investing activities	34,250	(112,624)
Net cash provided by financing activities	4	88,875
Increase (decrease) in cash and cash equivalents	$ 15,385	$ (35,137)

Operating Activities

Net cash used in operating activities was $18.9 million and $11.4 million for the three months ended March 31, 2026 and 2025, respectively. The net cash used in operating activities during the three months ended March 31, 2026 was primarily due to our reported net loss of $21.6 million, net of non-cash items (including unrealized losses on short-term investments, stock-based compensation expense, non-cash lease expense and amortization of discount on short-term investments) totaling $2.0 million and a $0.7 million net decrease of our net operating assets. The net cash used in operating activities during the three months ended March 31, 2025 was primarily due to our reported net loss of $9.3 million, net of non-cash charges (including unrealized losses on short-term investments, stock-based compensation expense, non-cash lease expense and amortization of discount on short-term investments) totaling $0.3 million and a $2.4 million net increase of our net operating assets. The increase in cash used in operations during the three months ended March 31, 2026 in comparison to the three months ended March 31, 2025 was primarily attributable to increased research and development activities.

Investing Activities

Net cash provided by investing activities during the three months ended March 31, 2026 was $34.3 million resulting from the sales and maturities of short-term investments during the period. Net cash used in investing activities was $112.6 million during the three months ended March 31, 2025 primarily as a result of the purchase of short-term investments during the period, offset by maturities of short-term investments during the period.

Financing Activities

Net cash provided by financing activities during the three months ended March 31, 2026 was $4,000 and resulted from sales of common stock under our employee equity plans. Net cash provided by financing activities during the three months ended March 31, 2025 was $88.9 million and resulted primarily from the proceeds from the sale and issuance of shares of our common stock in our IPO in February 2025 for proceeds of $91.1 million, offset by payments for IPO costs of $2.3 million.

Contractual Obligations and Other Commitments

There have been no material changes to our contractual obligations and other commitments from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Contractual Obligations and Other Commitments" included in our Annual Report on Form 10-K filed with the SEC on March 23, 2026.

During the normal course of our business, we enter into contracts for research and professional services, and for the purchase of lab supplies used in our research activities. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not separately presented.

Critical Accounting Estimates

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

There have been no material changes to our critical accounting policies and estimates from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Estimates" included in our Annual Report on Form 10-K filed with the SEC on March 23, 2026.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our cash and cash equivalents consist of cash held in readily available checking and money market accounts, as well as short-term debt securities. We are exposed to market risk related to fluctuations in interest rates and market prices. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, we do not believe a hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would have had a material impact on our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Foreign Currency

Net realized and unrealized gains and losses from foreign currency transactions are reported in other income (expense), net, in the unaudited condensed consolidated statements of operations and comprehensive loss. All of our employees and our operations are currently located in the United States and our expenses are generally denominated in U.S. dollars. However, we have contracted with and may continue to contract with non-U.S. vendors who we may pay in local currency. To date, the impact of foreign currency costs on our operations has been negligible for all periods presented and we have not had a formal hedging program with respect to foreign currency. Therefore, we do not believe a hypothetical 100 basis point increase or decrease in exchange rates during any of the periods presented would have had a material impact on our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

Item 4. Controls and Procedures.

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that 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. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective at the reasonable level of assurance as of March 31, 2026, the end of the period covered by this Quarterly Report.

Changes in Internal Control over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during the quarter ended March 31, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, 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, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors.

An investment in our common stock involves a high degree of risk. In deciding whether to invest, you should carefully consider and read the following risk factors, as well as the financial and other information contained in this Quarterly Report, including in Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations", of this Quarterly Report and in our unaudited condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report. The risk factors set forth below with an asterisk (*) next to the title contain changes to the description of the risk factors associated with our business previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2025. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations or prospects and cause the value of our common stock to decline, which could cause you to lose all or part of your investment. The risks described below are not the only ones facing us. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial also may become important factors that affect us.

Risk Factor Summary

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks that we face, follows this summary. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.
- Our business is heavily dependent on the successful development, regulatory approval and commercialization of our lead product candidate, ARD-101.
- The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed.
- Preclinical and clinical drug development involves a lengthy and expensive process, with uncertain timelines and outcomes, and results of earlier studies and trials may not be predictive of future trial results. If development of our product candidates is unsuccessful or delayed, we may be unable to obtain required regulatory approvals and we may be unable to commercialize our product candidates on a timely basis, if at all.
- Certain disorders we seek to treat, such as PWS, have low prevalence and it may be difficult to identify and enroll patients with these disorders. If we encounter difficulties or delays enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Our clinical trials may fail to demonstrate safety and efficacy of our product candidates, or serious adverse events or side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials, as well as investigator-initiated trials. If those third parties do not perform as contractually required, fail to satisfy legal or

regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.

- We rely completely on third parties to manufacture our clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA or comparable regulatory authorities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.
- If we are unable to obtain, maintain and enforce intellectual property protection directed to our current and any future technologies that we develop, others may be able to make, use or sell product candidates substantially the same as ours, which could adversely affect our ability to compete in the market.
- We face substantial competition, which may result in a smaller than expected commercial opportunity and/or others discovering, developing or commercializing products before or more successfully than we do.

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

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate the success of our business to date and assess our future viability. Since our inception in 2017, we have focused primarily on organizing and staffing our company, business planning, establishing our intellectual property portfolio, raising capital, identifying and developing our product candidates, conducting preclinical studies and, more recently, clinical trials, and providing general and administrative support for these operations. To date, we have not yet demonstrated our ability to successfully obtain regulatory approvals, manufacture a 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 commercialization. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We may also need to transition from a company with a research focus to a company capable of supporting commercial activities. Our inability to adequately address these risks and difficulties or successfully make such a transition could adversely affect our business, financial condition, results of operations and growth prospects.

****We have incurred significant losses since our inception and expect to incur losses over the next several years and may never achieve or maintain profitability.***

We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant losses since our inception and expect to continue to incur significant and increasing operating losses for at least the next several years. For the three months ended March 31, 2026 and 2025, we reported a net loss of $21.6 million and $9.3 million, respectively. As of March 31, 2026, we had an accumulated deficit of $137.5 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. ARD-101 will require substantial additional development time and resources before we would be able to apply for or receive marketing approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate that our expenses will increase substantially as we:

- conduct our ongoing and planned clinical trials of ARD-101 as well as initiate and complete additional clinical trials for other product candidates and programs;
- complete preclinical studies;
- pursue regulatory approval of our product candidates;
- seek to discover and develop additional clinical and preclinical product candidates;
- scale up our clinical, operational, regulatory and quality assurance capabilities;

- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing, regulatory, quality assurance and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

Even if we succeed in developing and obtaining marketing approval for one or more product candidates, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research, development and other expenditures to develop and market additional product candidates. If we fail to become and remain profitable, it would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

The development of biopharmaceutical product candidates is capital-intensive. We expect our expenses to increase substantially in connection with our ongoing and planned activities, particularly as we conduct our ongoing and planned preclinical studies and clinical trials of ARD-101 and our other product candidates and programs, and any future product candidates we may develop. Our expenses will increase substantially if our product candidates successfully complete early clinical and other studies and also could increase beyond expectations if the FDA or comparable foreign regulatory authorities require us to perform studies in addition to those that we currently anticipate. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. In addition, we will incur additional costs associated with operating as a public company. Furthermore, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

As of March 31, 2026, we had cash, cash equivalents and short-term investments of approximately $91.2 million. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our projected operations into mid-2027. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through equity offerings, debt financings or other capital sources, including potential grants, collaborations, licenses and other similar arrangements. Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Such financing may result in dilution to our stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business.

Our future capital requirements depend on many factors, including:

- the design, timing, costs, progress, and results of our planned and ongoing preclinical studies and clinical trials;
- whether the FDA or comparable foreign regulatory authorities accept our clinical trial designs and development, data from our planned and ongoing preclinical studies and clinical trials and other work as the basis for review and approval of our product candidates;
- the extent to which we develop, in-license or acquire other product candidates and technology;
- the timing, costs and outcome of seeking, obtaining and, if applicable, maintaining, FDA and comparable foreign regulatory approvals;
- the number and characteristics of product candidates that we pursue;

- our efforts to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the cost of pre-commercial activities and, if approved, commercialization activities related to our product candidates, including marketing, sales and distribution costs;
- the costs and timing associated with manufacturing our product candidates and establishing commercial supplies and sales, marketing and distribution capabilities;
- the cost of building or contracting a sales force in anticipation of commercialization;
- our ability to establish strategic collaborations, licensing 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;
- our need and ability to identify and retain key management and hire scientific, technical, business, clinical and clinical operations personnel;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems and validate large-scale data and document systems;
- the costs associated with being a public company;
- the timing, receipt and amount of sales of our product candidates, if approved; and
- potential unforeseen liabilities and payment milestones for current and future in-licensed programs.

We currently have an effective shelf Registration Statement on Form S-3 (File No. 333-294537) that became effective on April 3, 2026, which allows us to undertake various equity and debt offerings up to $400.0 million. In addition, on March 23, 2026, we entered into an Equity Distribution Agreement with Piper Sandler & Co. (the Agent), pursuant to which we may offer and sell from time to time through the Agent up to $150.0 million in shares of our common stock (the ATM Facility). As of March 31, 2026, we have not sold any shares of common stock under the ATM Facility.

Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and, if approved, commercialize our current and any future product candidates. Additional funding may not be available when we need them, on acceptable terms, or at all. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly or more dilutive. If adequate funds are not available to us on a timely basis or on terms we believe are acceptable, we may be required to:

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

We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise pursue on our own. To date, we have primarily financed our operations through the sale of equity securities. We will be required to seek additional funding in the future and currently intend to do so through public or private equity offerings or debt financings, credit or loan facilities, collaborations or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. If additional funding is not available when we need it or on acceptable terms, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition and results of operations.

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

Our business is heavily dependent on the successful development, regulatory approval and commercialization of our lead product candidate, ARD-101.

We currently have no products that are approved for commercial sale. Our lead product candidate, ARD-101, is an oral, largely gut-restricted small-molecule agonist of certain TAS2Rs expressed on luminally accessible enteroendocrine cells lining the gut for which we have initiated a Phase 3 clinical trial for hyperphagia associated with PWS. In February 2026, we voluntarily paused enrollment and dosing in the HERO trial and the open label extension (OLE) trial based on reversible cardiac observations in a healthy volunteer study. We are conducting a comprehensive review of the data and collaborating with the FDA to determine next steps and expect to provide further guidance in the second quarter of 2026. The success of our business, including our ability to finance our company and generate revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our lead product candidate. We cannot be certain that ARD-101 or any other current or future product candidates will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

We have not previously submitted an NDA to the FDA or any similar approval filing to a comparable foreign regulatory authority, for any product candidate. An NDA or other relevant regulatory filing must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. It may also necessitate a successful regulatory inspection of manufacturing facilities and/or clinical sites. We cannot be certain that our current or future product candidates will be successful in clinical trials. Further, even if they are successful in clinical trials, our current or future product candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights, as well as the availability of competitive products, whether there is sufficient third-party reimbursement and adoption by physicians.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and in select foreign countries. While the scope of regulatory approval generally is similar in other countries, in order to obtain separate regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of drugs, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions.

Before we can generate any revenue from sales of our lead product candidate, ARD-101, or any other current or future product candidates, we must undergo additional preclinical and clinical development, regulatory review and approval in one or more jurisdictions. In addition, if one or more of our product candidates are approved, we must ensure access to sufficient commercial manufacturing capacity and conduct significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and we may not have the financial resources to continue development of our product candidates. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- timely and successful completion of our preclinical studies and clinical trials, which may be significantly slower or more costly than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- successful enrollment of subjects in, and completion of, our clinical trials;
- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete and maintain investigational new drug applications (INDs) and IND-enabling studies and successfully submit INDs or comparable applications for our product candidates or any future product candidates;
- whether we are required by the FDA or comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and comparable foreign regulatory authorities, including the use of non-invasive or other novel endpoint to initially obtain market authorization for our product candidates or any future product candidates;

- our ability to demonstrate to the satisfaction of the FDA and comparable foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements, which may negatively impact the supply chain or cause other disruptions;
- the prevalence, incidence, duration and severity of potential side effects or other safety issues or adverse events experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and comparable foreign regulatory authorities;
- successful completion of required post-marketing approval commitments and requirements, if any, to the FDA and comparable foreign regulatory authorities;
- successful development of, or arrangements made with third party manufacturers for, our commercial manufacturing processes of any of our product candidates or future product candidates that receive regulatory approval;
- achieving and maintaining and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to manufacture adequate clinical trial and commercial supplies of our product candidates or any future product candidates to remain compliant and in good standing with regulatory agencies, develop, validate and maintain commercially viable manufacturing processes that comply with cGMPs;
- our ability to successfully develop a commercial strategy and thereafter commercialize our current or future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved drugs;
- the convenience of our treatment or dosing regimen and the degree to which physicians can prescribe and patients are able to comply with the recommended treatment regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or any future product candidates, if approved;
- patient demand for our product candidates, if approved, including patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- effectively competing with other products;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims; and
- our ability to build, train and maintain an organization of people who can successfully develop our product candidates.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates, if approved, to continue our business or achieve profitability.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign regulatory authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon

numerous factors, including the substantial discretion of the regulatory authorities. In addition, policies, regulations, and the type and amount of clinical data that the regulatory authority views as necessary for approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that we may never obtain regulatory approval for any product candidate we may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any product candidate in the United States until the product candidate receives regulatory approval from the FDA.

Prior to obtaining approval to commercialize any product candidate in the United States or abroad, we must demonstrate with sufficient evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities. Our approach is designed to target biological pathways associated with alleviating hunger, specifically by developing selective compounds targeting TAS2Rs, is unproven and may not result in marketable products. Although multiple studies have been conducted and are planned, to date, this mechanism has not been definitively proven to successfully treat hunger-associated conditions. Targeting TAS2Rs is a novel approach in a rapidly developing field, and there can be no assurance that we will not experience currently unknown problems or delays in developing our product candidates, that such problems or delays will not result in unanticipated costs, or that any such development problems can be solved. The FDA may also require us to conduct additional preclinical studies, clinical trials or other studies for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs.

Of the large number of products in development globally, only a small percentage successfully complete the FDA or comparable foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market our product candidates, which would adversely affect our business, financial condition, results of operations and prospects.

We have invested a significant portion of our time and financial resources in the development of our clinical and preclinical product candidates. Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize, our current and future product candidates in a timely manner.

Even if we eventually complete clinical testing and receive approval or other marketing authorization from the FDA or comparable foreign regulatory authority, the FDA or the comparable foreign regulatory authority may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA or the comparable foreign regulatory authority also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally propose, and the FDA or comparable foreign regulatory authority may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially and adversely impact our business and prospects.

In addition, the FDA and comparable foreign regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. There remains substantial uncertainty as to how the current U.S. administration will seek or continue to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. State governments may also attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. This uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. Such policy or regulatory changes through, for example, executive orders or legislation could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Preclinical and clinical drug development involves a lengthy and expensive process, with uncertain timelines and outcomes, and results of earlier studies and trials may not be predictive of future trial results. If development of our product candidates is unsuccessful or delayed, we may be unable to obtain required regulatory approvals and we may be unable to commercialize our product candidates on a timely basis, if at all.

Our product candidates, including ARD-101, are still in clinical development and their risk of failure is high. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans for the indications for which we intend to commercialize our product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the preclinical or clinical trial process. Success in

preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the safety and effectiveness of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and regimens. Success in preclinical studies and early or Phase 2 clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. Our product candidates may fail to show the required safety and effectiveness through clinical trials despite positive results in preclinical studies or having successfully advanced through initial clinical trials, particularly because we are targeting novel pathways that have not yet been tested in later-stage clinical trials.

A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after receiving promising results in earlier non-clinical or clinical trials. These setbacks have been caused by, among other things, non-clinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Product candidates in later stages of clinical trials may fail to show the desired safety and effectiveness traits despite having progressed through preclinical and earlier phase clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many sponsors that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We may incur additional costs and experience delays in ongoing clinical trials for our product candidates, and we do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of subjects on time or be completed on schedule, if at all. We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards (IRBs) and ethics committees (ECs) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts for our clinical trial protocols with prospective trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may fail to demonstrate statistical significance in early stage or Phase 2 clinical trials of our product candidates, which may impact the timing and design of late-stage clinical trials for such product candidates;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, we may be required or determine it is appropriate to expand enrollment in clinical trials, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our product candidates may have undesirable side effects, unforeseen adverse events, or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ECs to suspend or terminate the trials. For example, in February 2026, we voluntarily paused enrollment and dosing in the Phase 3 HERO trial and the OLE trial for ARD-101, and the POWER and STRENGTH clinical trials for ARD-201, based on reversible cardiac observations in a healthy volunteer study of ARD-101;
- we or our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or IRBs and ECs may require that we or our investigators suspend or terminate clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs representing the institutions at which such trials are being conducted, by a data monitoring committee for such trial or by the FDA or comparable foreign regulatory

authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate candidate product benefit, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, 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 or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site(s) and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, refusal to accept or rejection of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of our product candidates.

If we experience delays in the completion of any clinical trial of our product candidates or terminate any such clinical trial, the commercial prospects of our product candidates may be harmed, and our ability to generate drug revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may adversely affect our business, operating results, prospects or financial condition. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Certain disorders we seek to treat, such as PWS, have low prevalence and it may be difficult to identify and enroll patients with these disorders. If we encounter difficulties or delays enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to initiate or continue our planned clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible subjects to participate in these trials. For example, we are developing ARD-101 for the treatment of hyperphagia associated with PWS. PWS is a rare disease with a limited patient pool from which to draw. In February 2026, we voluntarily paused enrollment and dosing in the Phase 3 HERO trial and the OLE trial for ARD-101, and the POWER and STRENGTH clinical trials for ARD-201 based on reversible cardiac observations in a healthy volunteer study of ARD-101. We are conducting a comprehensive review of the data and collaborating with the FDA to determine next steps and expect to provide further guidance in the second quarter of 2026. There can be no assurance that we will be able to resume enrollment or dosing in these trials on a timely basis, or at all, which could further delay our clinical development timelines. Moreover, there is no guarantee that, if and when we resume any clinical trials, we may encounter further delays or difficulties in resuming enrollment and/or dosing, including due to our announcement of having voluntarily paused our clinical programs.

The timely completion of any clinical trial in accordance with its protocol depends, among other things, on our ability to enroll a sufficient number of subjects who remain in the study until its conclusion. We may experience difficulties in subject enrollment in our clinical trials for a variety of reasons. The enrollment of subjects depends on many factors, including:

- the subject eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the clinical trial's primary endpoints and the process for identifying subjects;
- the proximity of subjects to clinical sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the existing body of safety and efficacy data for the product candidates;
- the availability of competing commercially available products and other competing product candidates' clinical trials;

- the efforts to facilitate timely enrollment in clinical trials;
- the ability to monitor subjects adequately during and after treatment;
- clinicians' and subjects' perceptions as to the potential risks and benefits of the product candidate being studied in relation to other available products, including any approved or new products that may be approved for the indications we are investigating;
- other factors outside of our control, such as the effects of global economic and geopolitical conditions, for example, the war in Iran and other instability in the Middle East and other regions of the world;
- our ability to obtain and maintain patient informed consent;
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion; and
- our ability to timely manufacture and supply clinical supplies for our product candidates.

Our Phase 3 HERO trial, evaluating the effect of ARD-101 on hyperphagia-related behavior in PWS, was limited to subjects 10 years of age and older after reaching alignment with the FDA in October 2025 on a protocol amendment to change the minimum age of eligibility to participate in the trial from 13 to 10 years of age or older. In December 2025, we submitted an additional protocol amendment seeking to further lower the minimum age of eligibility to participate in the trial to 7 years of age. If we restart HERO or another trial to evaluate ARD-101 in PWS patients, certain factors may preclude us from receiving regulatory approval to treat younger pediatric subjects, including potential disagreements regarding appropriate dose and dose escalation, product presentation for possibly lower doses, validity of patient-reported outcomes in younger, actively growing patients, and avoiding inappropriate hunger suppression in these growing individuals. We can neither predict if the FDA or comparable foreign regulatory authorities will approve the use of our product candidates or programs in younger pediatric subjects, nor provide an estimate for the timing of such approval, if any. Furthermore, if the FDA or comparable foreign regulatory authorities do not approve the use of our product candidates or programs in this population, such product candidates or programs will not be labeled for use in these subjects. Given that the median lifespan of PWS patients is currently 30 years, the size of our market opportunity in this indication will be more limited if ARD-101 is not ultimately approved in pediatric patients and does not result in a significant increase in patient lifespan. Following the voluntary pause of our clinical programs in February 2026, we are reviewing the HERO trial design and protocol in collaboration with the FDA and the previously agreed protocol elements may be revisited.

In addition, our clinical trials may compete for patients that are already taking existing products approved for the indications we are seeking to treat and also 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 subjects available to us, because some subjects who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Furthermore, if subjects drop out of our clinical trials, miss scheduled doses or follow-up visits, or otherwise fail to follow clinical trial protocols, the integrity of data from our clinical trials may be compromised or not accepted by the FDA or comparable foreign regulatory authorities, which would represent a significant setback for the applicable program. In addition, we may rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

As a result, delays in subject enrollment or inability to identify and enroll a sufficient number of eligible subjects may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

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

From time to time, we may publish interim topline or preliminary results from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following the availability of more data or 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, interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could adversely affect our business prospects and may cause the trading price of our common stock to fluctuate significantly.

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 investors 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 adversely affect our business, operating results, prospects or financial condition.

Our clinical trials may fail to demonstrate safety and efficacy of our product candidates, or serious adverse events or side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.

Unforeseen adverse events or undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication. Our clinical trials of ARD-101 for the treatment of hyperphagia associated with PWS rely on measurement of reduction of hyperphagia behavior based on HQ-CT scores, which are typically caregiver reported questionnaires. Because these questionnaires rely on subjective caregiver feedback, responses can be influenced by factors outside of our control, and can vary widely from day to day for a particular patient/caregiver, and from patient to patient and site to site within a clinical trial.

In February 2026, we voluntarily paused enrollment and dosing in the HERO trial following reversible cardiac observations identified in a healthy volunteer study of ARD-101. While these observations were not reported as serious adverse events, they may nevertheless lead to additional regulatory scrutiny or changes to our development program.

If our product candidates are associated with adverse events in clinical trials or have side effects or other characteristics that are serious or unexpected, we may need to abandon their development or limit development to more narrow uses in which the adverse events, side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. We may also be required to modify our trial plans based on findings in our ongoing clinical trials. The FDA may also require that we conduct additional studies regarding the safety and efficacy of our product candidates, which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of such product candidates.

Treatment-related side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Furthermore, we may be required to expend time and incur costs 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. Any of these occurrences may adversely affect our business, operating results, prospects or financial condition. Moreover, if any serious side effects or other adverse events were to occur in any of our clinical programs, we could be subject to negative publicity and our company and reputation may be harmed.

Additionally, if one or more of our product candidates receives marketing approval, and we or others identify adverse events or undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- we may discontinue marketing of the product candidate, or decide to remove the product candidate from the marketplace, if approved;
- regulatory authorities may withdraw or change their approvals of that product candidate;
- regulatory authorities may require additional warnings on the label or limit access of that product candidate to selective specialized centers with additional safety reporting and with requirements that subjects be geographically close to these centers for all or part of their treatment;

- we may be required to send "dear doctor" letters to treatment providers or disseminate a medication guide outlining the risks of the product candidate for subjects, or to conduct post-marketing studies;
- we may be required to change the way the product candidate is administered;
- we may need to conduct a recall;
- 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;
- we may not be able to achieve or maintain third-party payor coverage and adequate reimbursement; and
- the product candidate may become less competitive, and our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or comparable foreign regulatory authorities in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could adversely affect our business, operating results, prospects or financial condition.

As an organization, we have not previously conducted pivotal clinical trials, and we may be unable to do so successfully for any product candidates we may develop.

We will need to successfully complete pivotal clinical trials in order to obtain product approval from the FDA or comparable foreign regulatory authorities to market ARD-101 or any other current or future product candidate. Carrying out pivotal clinical trials is a complicated process. We initiated a Phase 3 HERO clinical trial in hyperphagia associated with PWS in December 2024. In February 2026, we voluntarily paused enrollment and dosing in the HERO trial based on reversible cardiac observations in a healthy volunteer study. We are conducting a comprehensive review of the data and collaborating with the FDA to determine next steps. If the FDA determines that additional nonclinical studies, dose modifications, enhanced monitoring or other protocol changes are required, our clinical development timelines could be significantly delayed. We no longer anticipate topline data from the HERO trial in the third quarter of 2026, and the timing of additional staffing and operational expansion may be delayed as we evaluate next steps following the voluntary pause of our clinical programs. We expect to provide further guidance in the second quarter of 2026. Additionally, because ARD-201 contains ARD-101 as a component, we have also voluntarily paused the POWER and STRENGTH clinical trials for ARD-201.

As an organization, we have not previously successfully conducted any later stage or pivotal clinical trials. In order to do so, we have expanded our clinical management and regulatory capabilities, including hiring clinical, regulatory and quality personnel, and we expect to potentially need to expand our clinical management and regulatory capabilities, but may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our later stage or pivotal clinical trials. See the subsection titled "—Risks Related to Our Dependence on Third Parties—We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials, as well as investigator-initiated trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates." Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission of an NDA and approval of ARD-101 or any other current or future product candidates. In addition, no product candidate can receive FDA approval unless clinical trials show both safety and efficacy for each target indication in accordance with FDA or foreign country standards. We plan to conduct a number of clinical trials for multiple product candidates in parallel over the next several years depending on the outcome of our ongoing evaluation of our voluntarily paused clinical programs. This may be a difficult process to manage with our limited resources and may divert the attention of management. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates, which could adversely affect our business, operating results, prospects or financial condition.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we focus on development programs and product candidates that we identify for specific indications. As such, we are currently primarily focused on the development of ARD-101 for the treatment of hyperphagia associated with PWS. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications for our product candidates that later prove to have greater commercial potential. Moreover, in February 2026, we

voluntarily paused enrollment and dosing in the Phase 3 HERO trial and the OLE trial for ARD-101, and the POWER and STRENGTH clinical trials for ARD-201, based on reversible cardiac observations in a healthy volunteer study of ARD-101. We are conducting a comprehensive review of the data and collaborating with the FDA to determine next steps and expect to provide further guidance in the second quarter of 2026. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. We must continually assess the potential commercial viability of our research programs and product candidates, and we may decide to pause, discontinue or deprioritize development of any of our product candidates based upon such assessments, even if we obtain positive data from our product candidates in preclinical studies and clinical trials. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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, comparable regulatory authorities in foreign jurisdictions must also approve the regulatory submission, preclinical studies, clinical trials, manufacturing, marketing and promotion 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 drugs is also subject to approval.

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 drugs 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, which would adversely affect our business, prospects, financial condition and results of operations.

We have conducted and may plan to conduct certain clinical trials for our product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

Prior to the voluntary pause of our clinical programs, we were conducting, and potentially plan to conduct again, certain clinical trials of ARD-101 outside the United States, including, but not limited to, in the United Kingdom, South Korea, Canada and Australia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be 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. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical power, must be met. 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. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, we would need to conduct additional trials, which could be costly and time-consuming.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, and advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by

the FDA and other comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, product tracking and tracing requirements, requirements regarding the distribution of samples to physicians and recordkeeping and GCP requirements for any clinical trials that we conduct post-approval.

Even if we receive approval for our product candidates, they may be subject to limitations on the approved indicated uses for which the drug may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require us to adopt a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential subject, which may include, among other things, a communication plan to health care practitioners, patient education, extensive subject 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, if we or others later identify undesirable side effects caused by any drug that we develop alone or with collaborators.

Later discovery of previously unknown problems with a product candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things, the following actions by regulators:

- the FDA issuing warning letters or untitled letters;
- mandating modifications to promotional materials or requiring us to provide corrective information to healthcare practitioners, or requiring other restrictions on the labeling or marketing of such product;
- requiring us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for non-compliance;
- seeking an injunction or imposing civil or criminal penalties or monetary fines;
- being sued and held liable for harm caused to subjects or patients;
- suspending, withdrawing or modifying regulatory approval;
- suspending or modifying any ongoing clinical trials or requirement to conduct additional clinical trials;
- refusing to act on pending applications, supplements to applications or comparable foreign applications filed by us;
- suspending or imposing restrictions on operations, including costly new manufacturing requirements; or
- seizing or detaining products, refusing to permit the import or export of products or requiring us to initiate a product recall.

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

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission (the FTC), the Department of Justice, the U.S. Department of Health and Human Services Office of Inspector General, state attorneys general, members of the U.S. Congress and the public. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability.

Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our drugs for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or comparable foreign bodies. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees and/or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions or civil or criminal penalties.

The FDA's and comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, the U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. The Loper decision also may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, 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, which could adversely affect our business, operating results, prospects or financial condition.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages, government shutdowns or global health concerns could negatively impact our business operations, regulatory interactions and access to capital.

Significant disruptions to the operations of government agencies, including from prolonged or repeated shutdown of the federal government, could adversely affect our business, financial condition and results of operations. For example, on October 1, 2025, the U.S. government shut down for 43 days, during which time certain regulatory agencies, such as the FDA and the SEC, furloughed certain employees and stopped critical activities. On October 10, 2025, the U.S. government implemented substantial layoffs and workforce reductions in connection with the federal government shutdown, which resulted in the suspension or delay of various government-funded programs. The ability of the FDA to review and approve new products, to provide feedback on clinical trials and development programs, to meet with sponsors and to otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels, reductions in workforce, ability to hire and retain key personnel and accept the payment of user fees, substantial changes in leadership and shifting policy priorities as a result of changes in the presidential administration and its appointees tasked to oversee the agency, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result and may continue in the future. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including as a result of reductions in force, significant organizational changes, substantial leadership departures, and policy changes, 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, the current U.S. administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs. Additionally, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough certain employees and stop certain critical activities. The current U.S. administration also has taken steps to reduce the number of federal employees by establishing voluntary termination programs, by position eliminations or by involuntary terminations. If funding for the FDA is reduced, if the FDA workforce is reduced, or if government shutdowns reoccur, any of these factors 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, a future shutdown of the U.S. federal government could materially impact the operations of the SEC. For example, during the most recent U.S. federal government shutdown, the SEC announced that it would not declare registration statements effective. In the event of a future shutdown, the SEC may operate with limited staff or suspend certain functions altogether, which could delay the review or effectiveness of our filings, including registration statements or other financing-related disclosures. Such delays could adversely affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

In addition, future government shutdowns or funding freezes could negatively affect broader business operations and economic conditions and cause delays in or suspension of manufacturing facility and shipping operations, which could adversely affect our clinical trials and supply of product candidates. If these disruptions reoccur or worsen, our business, financial condition, results of operations and ability to execute our strategic plans could be materially and adversely affected.

The FDA or comparable foreign regulatory authorities may also face delays or resource constraints relating to foreign inspections, such as those that occurred during the COVID-19 pandemic. In response, such agencies may shift inspection priorities, may turn to remote regulatory assessments, or may issue other policies that could affect product approval timelines, which could have a material adverse effect on our business. A U.S. government shutdown or reduction in FDA funding or workforce may also affect inspection-related activities.

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 regulatory application submission, potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics. Such changes carry the risk that they will not achieve their 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 agreement. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

We may not be successful in our efforts to identify or discover additional product candidates in the future.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the pharmacological properties that we desire or attractive pharmacokinetics; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to obtain product revenue in future periods for such programs.

We have received Orphan Drug Designation and Rare Pediatric Disease Designation for ARD-101 for the treatment of PWS, and we may seek Orphan Drug Designation and/or Rare Pediatric Disease Designation for some or all of our other product candidates. However, we may not receive either such designation, and we may not be able to maintain Orphan Drug Designation or Rare Pediatric Disease Designation or obtain a Rare Pediatric Disease priority review voucher or orphan drug exclusivity for ARD-101, which could limit the potential profitability of our product candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs intended to treat relatively small patient populations as orphan drug products. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for granting funding towards clinical trial costs, tax advantages and application fee waivers. If a drug or biologic with an Orphan Drug Designation subsequently receives marketing approval for the indication for which it has such designation, the product may be entitled to an expanded period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States. An orphan drug benefiting pediatric patients can qualify as a drug for a Rare Pediatric Disease Designation as well. If so designated, the sponsor of the Rare Pediatric Disease designated product may be eligible for a rare pediatric disease priority review voucher, which would be issued in connection with FDA approval for the designated product. Under the Federal Food, Drug, and Cosmetic Act (the FDCA), a rare pediatric disease product application may be eligible for a rare pediatric disease priority review voucher if the drug receives marketing approval before September 30, 2029.

The FDA granted us an Orphan Drug Designation and a Rare Pediatric Disease Designation for the use of ARD-101 in PWS in August 2023, and we may also seek Orphan Drug Designation for some or all of our other product candidates. However, we may be unsuccessful in obtaining Orphan Drug Designation and/or Rare Pediatric Disease Designation for other product candidates, and we may be unable to obtain or maintain the benefits associated with Orphan Drug Designation or Rare Pediatric Disease Designation for ARD-101 or other product candidates for which we may receive such designations. The exclusivity granted under the Orphan Drug Designation may not effectively protect ARD-101 from competition because different drugs can be approved for the same condition, and orphan drug exclusivity does not prevent the FDA from approving the same or a different drug for another indication. The FDA may be able to subsequently approve a later application for the same drug for the same condition before the expiration of the seven-year exclusivity period if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan

designation. Moreover, orphan-drug-exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Neither Orphan Drug Designation nor Rare Pediatric Disease Designation shortens the development time or regulatory review time of a drug and does not give the drug any advantage in the regulatory review or approval process. Additionally, even if we obtain orphan drug designation for a product candidate, we may not be able to obtain orphan drug exclusivity for that product candidate. Similarly, we may not be able to obtain a rare pediatric disease priority review voucher for any product candidate for which we receive a Rare Pediatric Disease Designation, particularly if such product candidate does not receive marketing approval before September 30, 2029 and the program is not further extended.

A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval in the United States.

We may apply for a Breakthrough Therapy designation for ARD-101 and any other current or future product candidates for one or more indications when we have placebo-controlled data and we believe that the clinical data may support such a designation for one or more product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition with unmet medical need, and preliminary clinical evidence indicates that the drug, or biologic, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs and biologics designated as Breakthrough Therapies by the FDA may also be eligible for rolling review (submissions of portions of an application before the complete marketing application is submitted) and priority review.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and determine not to make such designation. For example, we previously applied for Breakthrough Therapy designation for ARD-101 for the treatment of hyperphagia associated with PWS; however, the FDA noted that we would need to provide additional information in order to support such a Breakthrough Therapy designation. We may determine to submit a new request for Breakthrough Therapy designation for ARD-101 for the treatment of hyperphagia associated with PWS that includes the additional information requested by the FDA when available. However, there can be no assurances that the FDA would consider any such additional information to be sufficient or otherwise determine to grant a Breakthrough Therapy designation for ARD-101 for the treatment of hyperphagia associated with PWS. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product no longer meets the conditions for such qualification.

We may not be successful in pursuing or maintaining fast track or other expedited regulatory designations for our product candidates, and such designations may not actually lead to a faster development or regulatory approval process.

We may apply for fast track designation, priority review or accelerated approval status for ARD-101 or any other current or future product candidates. However, even if we receive fast track designation, priority review or accelerated approval status or other accelerated review designation for one or more of our product candidates, these designations do not assure that we will experience a faster development process, regulatory review or regulatory approval process compared to conventional FDA procedures. In addition, the FDA may withdraw a fast track, priority review, accelerated approval status or other accelerated review designation if it believes that the status or designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product candidate. Access to an expedited program may expedite the development or approval process, but it does not change the standards for approval.

Furthermore, although we may pursue additional opportunities to accelerate the development of certain of our product candidates through one or more of the FDA's expedited program designations, we cannot be assured that any of our product candidates will qualify for such programs. The FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program.

Risks Related to Our Dependence on Third Parties

We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials, as well as investigator-initiated trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.

We rely and intend to rely in the future on third-party clinical investigators, CROs, and clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current or future product candidates. In addition, third parties are conducting and we expect will continue to conduct investigator-initiated trials with our product candidates. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties may have contractual relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, partners or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays and challenges that are outside of our control.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on the CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies is conducted in accordance with GLPs, and clinical trials are conducted in accordance with GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once an NDA or biologics license application is submitted to the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CROs. In addition, our manufacturers are required to adhere to cGMPs, which include testing, control, and documentation requirements. If we, our CROs, clinical trial sites, manufacturers or other third parties fail to comply with applicable GCP, cGMPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP or cGMP regulations. Failure to comply with these regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, withdrawal of approvals previously obtained and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would limit our ability to operate and could increase our costs which may have a material adverse effect on our business. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

In the event we need to repeat, extend, delay or terminate our clinical trials because these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, and we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management's time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator’s technology or intellectual property or require us to stop development of those product candidates completely.

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

We rely completely on third parties to manufacture our clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA or comparable regulatory authorities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or internal capability to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the internal resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technology required to manufacture our product candidates may be unique to the original manufacturer and we may have difficulty transferring such skills or technology to another third party. The process of changing manufacturers is extensive and time-consuming and could cause delays or interruptions in our product candidate supply. Further, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with all applicable regulations and guidelines, including cGMPs, and that the post-change material is comparable to pre-change. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our product candidates and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We, or our manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we or our manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could adversely affect our business, operating results, prospects or financial condition.

We, or our manufacturing partners, may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from participants treated with products from these different facilities, in our product registrations. Further, our third-party manufacturers may not be able to manufacture our product candidates or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

We rely on third-party manufacturers to develop, validate, and operate the manufacturing processes for our products. Process validation can be complex and may be affected by factors outside of our direct control, including equipment performance, process variability, and challenges in scaling production. If our third-party manufacturers are unable to successfully develop or validate manufacturing processes, or to maintain validated processes, we may experience delays in production, increased costs, or disruptions in supply. Process validation may take longer than anticipated, may reveal deficiencies requiring remediation, or may ultimately not

be achievable with our current third-party manufacturers, any of which could materially delay or prevent the commercial launch of our future product candidates. In addition, failure to meet applicable regulatory requirements could result in regulatory actions.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. We have not entered into long-term agreements with our current contract manufacturers or with any alternate fill/finish suppliers, and though we intend to do so prior to commercial launch in order to ensure that we maintain adequate supplies of finished drug products, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. Our product candidates, and any drugs that we may develop, may compete with other product candidates and drugs for access to manufacturing facilities. Qualifying and validating such manufacturers may take a significant period of time and reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible increase in costs for the raw materials for our product candidates; and
- the possible termination or nonrenewal of any agreement by any third party at a time that is costly or inconvenient for us.

Under recent legislation, certain third-party manufacturers and other third parties (frequently China-based companies) may be considered a "biotechnology company of concern." If a third-party manufacturer receives such a designation, it may restrict the ability of U.S. companies like us to purchase services or products from, collaborate with, or otherwise work with such manufacturers. For example, it may delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. Such disruption could have adverse effects on the development of our product candidates.

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, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supply of our products.

We have entered into collaborations with third parties for the development of certain potential product candidates, and we may seek additional collaborations in the future for the development and commercialization of these or other potential candidates. If our collaborations are not successful, our ability to develop and commercialize our product candidates could be adversely affected.

We currently have collaborations with third parties to develop certain of our potential product candidates, although none of these collaborations relate to ARD-101. In the future, we may seek collaboration arrangements for the commercialization, or potentially for the development, of other product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. For example, certain disease areas that we believe our product candidates address require large, costly and later-stage clinical trials, which a collaboration partner may be better positioned to finance and/or conduct.

If we enter into any additional such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- 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 any product candidates that achieve regulatory approval 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, that 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 if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may seek to amend or modify the terms of any collaboration;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary 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;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may own or co-own intellectual property covering product candidates and other research that result from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property and may not be able to commercialize such intellectual property without their consent;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such 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 for the convenience of the collaborator and, if terminated, we could be required to raise 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 were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to subjects in our clinical trials, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional 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 such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may

not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue.

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

If conflicts arise between our collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Current or future collaborators or strategic partners may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations.

Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of products. Furthermore, competing products, either developed by our current or future collaborators or strategic partners or to which our collaborators or strategic partners may have rights, may result in the withdrawal of partner support for our product candidates. Any of these developments could harm our product development efforts, which could adversely affect our business, operating results, prospects or financial condition.

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

Reliance on third parties to manufacture or commercialize our current or any future product candidates, and on collaborations with additional third parties for the development of our current or any future product candidates, requires us to share trade secrets with these third parties. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, services agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any third-party collaborators. A competitor's discovery of our trade secrets could adversely affect our business, operating results, prospects or financial condition.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product candidates, technology and product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and confidential information, however, may be difficult to protect. We seek to protect our trade secrets, know-how and confidential information, including our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted

physical and technological security measures. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information, including to competitors. In addition, competitors or other third-parties may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite our 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. Recourse we take against such misconduct may not provide an adequate remedy to fully protect our interests. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our product candidates that we consider proprietary. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information, which could harm our competitive position.

Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

The operations of our suppliers, some of which may source raw materials and other supplies outside of the United States, are subject to additional risks that are beyond our control and that could adversely affect our business, financial condition, results of operations and prospects.

Currently, some of our suppliers may source raw materials and other supplies outside of the United States. As a result, we may be subject to risks associated with doing business abroad, including:

- political unrest, war, outbreaks of hostility, terrorism, labor disputes, and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality and safety standards, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA or comparable foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional, or local public health crises or other emergencies or natural disasters;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements, which may negatively impact the supply chain or cause other disruptions;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all, and inhibit our suppliers' ability to procure certain materials, any of which could adversely affect our business, operating results, prospects or financial condition.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain and enforce intellectual property protection directed to our current and any future technologies that we develop, others may be able to make, use or sell product candidates substantially the same as ours, which could adversely affect our ability to compete in the market.

The market for pharmaceuticals and biopharmaceuticals is highly competitive and subject to rapid technological change. Our success depends, in part, upon our ability to maintain a competitive position in the development and protection of technologies and

any future product candidates for use in these fields and upon our ability to obtain, maintain and enforce our intellectual property rights. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products that misappropriate our technology and/or infringe our intellectual property to unfairly and illegally compete with any of our product candidates. Given the amount of time required for the development, testing and regulatory review of new planned products, patents protecting such products might expire before or shortly after such products are commercialized. If we are unable to protect our intellectual property and proprietary rights, our competitive position and our business could be harmed, as third parties may be able to make, use or sell products that are substantially the same as any product candidates we may sell without incurring the sizeable development and licensing costs that we have incurred, which would adversely affect our ability to compete in the market. We use a combination of patents, trademarks, know-how, confidentiality procedures and contractual provisions to protect our proprietary technology and that of our licensors. However, these protections may not be adequate and may not provide us with any competitive advantage. For example, patents may not issue from any of our or our licensors' currently pending or any future patent applications, and our or our licensors' issued patents and any future patents that may issue may not survive legal challenges to their scope, validity or enforceability or provide significant protection for us.

To protect our proprietary position, we file patent applications in the United States and abroad related to our product candidates that we consider important to our business. The patent application and approval process is expensive, time-consuming and complex. We may not be able to file, prosecute and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, depending on the terms of any future license or collaboration agreements to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Furthermore, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Thus, we cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents will effectively prevent others from commercializing competing technologies and product candidates.

The USPTO, international patent offices or judicial bodies may deny or significantly narrow claims made under our patent applications, and our issued patents may be successfully challenged, may be designed around or may otherwise be of insufficient scope to provide us with protection for our drugs or combination therapies.

Further, the USPTO, international trademark offices or judicial bodies may deny our trademark applications and, even if published or registered, these trademarks may not effectively protect our brand and goodwill. Like patents, trademarks also may be successfully opposed or challenged.

We cannot be certain that the steps we have taken will prevent unauthorized use or unauthorized reverse engineering of our technology. Moreover, third parties may independently develop technologies that are competitive with ours and such competitive technologies may or may not infringe our intellectual property. The enforcement of our intellectual property rights also depends on the success of any legal actions we may take against these infringers in the respective country or forum, but these actions may not be successful. As with all granted intellectual property, such intellectual property may be challenged, invalidated or circumvented, may not provide protection and/or may not prove to be enforceable in actions against specific alleged infringers.

Even if our patents are determined by a court to be valid and enforceable, they may not be interpreted sufficiently broadly to prevent others from marketing products similar to ours or designing around our patents. For example, third parties may be able to make products that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our or our licensors' issued patents or patent applications when issued may not cover our product candidates or any future product candidates that we develop. We may not have freedom to commercialize unimpeded by the patent rights of others. Third parties may have patents that dominate, block or are otherwise relevant to our technology. In addition, there may be prior public disclosures or other art that could be deemed to invalidate one or more of our patent claims. We may not develop additional proprietary technologies in the future, and, if we do, they may not be patentable.

We may not be able to correctly estimate or control our future operating expenses in relation to obtaining intellectual property, enforcing intellectual property and/or defending intellectual property, which could affect operating expenses. Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, including the costs of preparing, filing, prosecuting, defending and enforcing patent and trademark claims and other intellectual property-related costs, including adverse proceedings and litigation costs.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of our current or future collaborators to develop, manufacture, market and sell our current and any future product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. Because the intellectual property landscape in the industry in which we participate is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our product candidates infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

Our product candidates and other proprietary technologies we may develop may infringe existing or future patents owned by third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technologies, including interference or derivation, post-grant review (PGR) and inter partes review (IPR) proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, a court of competent jurisdiction may not invalidate the claims of any such U.S. patent. If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technologies. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technologies or product candidate, or redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could adversely affect our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Third parties asserting their patent or other intellectual property rights against us may also seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates or force us to cease some of our business operations. Defense of these 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, cause development delays, and may impact our reputation.

Many of our employees were employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees 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 employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer.

In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our licensees and other parties with whom we have business relationships, and we may be required

to indemnify those parties for any damages they suffer as a result of these claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Additionally, during the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, programs or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

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

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon 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 as a result of questions regarding co-ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. 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 management and other employees.

We or our licensors may in the future rely on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that we or our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our patents, including in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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

As is common in the pharmaceutical and biotechnology industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, universities or other pharmaceutical or biotechnology companies including our competitors or potential competitors. These employees and consultants may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such other current or previous employment. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, which could adversely affect our business. Such intellectual property could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or drugs and combination therapies. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our current or future product candidates.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our current or future product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or at all. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and expenses and development delays, even if we were able to develop such alternatives, which may not be feasible.

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

We license or otherwise have access to patent rights from third-party owners. Such licenses or other arrangements may be subject to early termination if we fail to comply with our obligations in our agreements with third parties, which could result in the loss of rights or technology that are material to our business.

We are and may become a party to licenses and other agreements that give us rights to third-party intellectual property that are necessary or valuable for our business, and we may enter into additional licenses or other agreements in the future. Under these agreements, we are or may be obligated to pay the counterparties' fees, which may include annual license fees, milestone payments, royalties, a percentage of revenues associated with the applicable technology and a percentage of sublicensing revenue. In addition, under certain of such agreements, we are or may be required to diligently pursue the development of products using the applicable technology. If we fail to comply with these obligations and fail to cure our breach within a specified period of time, the counterparty may have the right to terminate the applicable agreement. Termination of this agreement, or reduction or elimination of our rights under it or any other agreement, may result in our having to negotiate new or reinstated arrangements on less favorable terms, or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could adversely affect our business, operating results, prospects or financial condition.

We may rely on third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves.

The risks described elsewhere pertaining to our intellectual property rights also apply to any intellectual property rights that we may license, and any failure by us or any future licensor to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, any of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our intellectual property licensed from third parties may be subject to retained rights.

Our future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for non-commercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Government agencies may provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property. The U.S. federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (the Bayh-Dole Act); these include the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products. While it is our policy to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including U.S. Supreme Court decisions, that have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

Further, we may not be aware of all third-party intellectual property rights potentially relating to our research programs and product candidates, or their intended uses, and as a result the potential impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the potential impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. While we are not aware of any third-party patents or patent filings that would block commercialization of our product candidates, we have not conducted a freedom-to-operate search or analysis for any of our current product candidates, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our product candidates. Thus, we cannot guarantee that our current product candidates, or our commercialization thereof, do not and will not infringe any third party's intellectual property. Because patent applications are maintained as confidential for a certain period of time (for example, patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all), until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that our product candidates may infringe. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. We have pending U.S. and foreign patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;

- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; and/or
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates.

Our patents or pending patent applications may be challenged in the courts or patent offices in the United States and other foreign jurisdictions. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in PGR procedures, derivations, reexaminations, or inter parties review proceedings, in the United States or oppositions or similar proceedings in foreign jurisdictions, challenging our patent rights. The legal threshold for initiating such proceedings may be low, so that even proceedings with a low probability of success might be initiated. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. In addition, we may rely on more than one patent to provide multiple layers of patent protection for our product candidates. If the latest-expiring patent is invalidated or held unenforceable, in whole or in part, the overall protection for the product candidate may be adversely affected. For example, if the latest-expiring patent is invalidated, the overall patent term for our product candidate could be adversely affected.

As a result, only limited protection may be available, and our patent portfolio may not provide us with sufficient rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that one or more patent of ours or any of our current licensors or future licensors is not valid or is unenforceable, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our or our licensors' patents at risk of being invalidated or interpreted narrowly, which may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products, and could put our or our licensors' patent applications at risk of not issuing. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at our products, the defendant could counterclaim that our or our licensors' patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could also include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our or our licensors' patents covering one or more of our product candidates, we could lose a part, and perhaps all, of the patent protection covering such candidate. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our products in one or more foreign countries. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may not be able to prevent, alone or with our potential licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our products to market.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technologies or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.

Patent terms may be inadequate to establish our competitive position on our product candidates for an adequate amount of time. If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Patent terms may be shortened or lengthened by, for example, terminal disclaimers, patent term adjustments, supplemental protection certificates and patent term extensions, but the life of a patent, and the protection it affords, is limited. Non-payment or delay in payment of patent fees, maintenance fees or annuities, delay in patent filings or delay in extension filings (including any patent term extension or adjustment filings), whether intentional or unintentional, may result in the loss of patent rights important to our business. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic versions. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents directed towards such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours for a meaningful amount of time, or at all.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our owned or licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) and similar legislation in the EU and certain other jurisdictions. The Hatch-Waxman Act permits, in certain cases, a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within

applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and the amount of available extension to any extension-eligible patent which claims a product, a method of using a product or a method of manufacturing a product, depends on a variety of factors, including the date on which the patent issues and certain dates related to the regulatory review period. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and non-clinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

We expect to receive five years of new chemical entity exclusivity under the Hatch-Waxman Act; however, because the denatonium active moiety is off-patent, a third party could obtain NDA approval for a denatonium drug prior to our NDA approval. In this case, we would not receive five years of exclusivity.

Further, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the AIA), could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The AIA includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, re-define prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, PGR, IPR and derivation proceedings.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents and patents that we or our licensors might obtain in the future. We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

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 licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary effect (the Unitary Patent). Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court (the UPC). As the UPC is a relatively new court system, there is little precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the

jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of the unitary patent system.

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 current or future trademarks or trade names may be challenged, infringed, circumvented, declared generic or descriptive, or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we propose or have proposed to use with our 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 a comparable foreign regulatory authority objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. 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. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as that in the United States or Europe. These products may compete with our product candidates, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, which could make it difficult for us to stop the infringement of our future patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. 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.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our owned or licensed pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our owned or licensed patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our owned or licensed patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our owned or licensed patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;

- we may be required to coordinate with licensors on enforcement of our patents;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application and secure an issued patent covering such intellectual property; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

Should any of these events occur, they could adversely affect our business, operating results, prospects or financial condition.

Risks Related to Legal and Regulatory Compliance Matters

Our relationships with customers, physicians, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, other healthcare laws and regulations and health data privacy and security laws and regulations, contractual obligations and self-regulatory schemes. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

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. Our current and future arrangements with healthcare providers, third-party payors and customers can expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research and, if approved, sell, market and distribute our products. In particular, the research of our product candidates, as well as the promotion, sales, marketing and business arrangements of our product candidates, is subject to extensive laws designed to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and serious harm to our reputation. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other;
- the federal civil and criminal false claims laws, including the federal False Claims Act, or FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government healthcare programs if they are deemed to "cause" the submission of false or fraudulent claims. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the healthcare fraud statute under HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and its implementing regulations, mandates, and, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of

protected health information (PHI), including individually identifiable health information, as defined under HIPAA, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities, which include certain health care providers, health plans and healthcare clearinghouses, that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information and other personal data in certain circumstances, some of which are more stringent or otherwise different than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties;

- the federal Physician Payments Sunshine Act and its implementing regulations, which require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and local laws that require the registration of pharmaceutical sales representatives.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal, state and foreign enforcement bodies regularly scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, significant fines and penalties and settlements in the healthcare industry. Ensuring that business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and may divert our management's attention from the operation of our business.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations 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 regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, 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, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could adversely affect our business, operating results, prospects or financial condition.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the

need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increase the possibility that a healthcare company may run afoul of one or more of the requirements.

Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (collectively, the ACA), was enacted in the United States, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program (the MDRP) are calculated for drugs and biologics that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the MDRP, extended manufacturer Medicaid rebate obligations to utilization by individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and biologics, and established a new Medicare Part D coverage gap discount program. Since its enactment, there have been judicial, congressional, and executive branch challenges to the ACA, which have resulted in delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress.

In addition, there have been a number of health reform initiatives that have impacted the ACA. For example, on August 16, 2022, the Inflation Reduction Act (the IRA) became law, which, among other things, extended enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminated the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. In addition, the IRA imposes new manufacturer financial liability on certain drugs under Medicare Part D, allowing the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, subject to certain exemptions applicable to orphan drugs. It is possible that the ACA will be subject to judicial or congressional challenges or legislative modifications in the future. It is unclear how such challenges or modifications, and the healthcare reform measures of the current administration, will impact the ACA and our business.

For example, on November 27, 2024, the Biden administration issued a proposed rule entitled *Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.* The Centers for Medicare & Medicaid Services (CMS) proposed that anti-obesity medications (AOMs), when used for weight loss or chronic weight management for the treatment of obesity, would no longer be excluded from Part D coverage. The aforementioned proposal would also apply to the Medicaid program. The Trump Administration did not finalize the proposal; however, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2032 unless additional Congressional action is taken. In certain countries outside the United States, reimbursement for products that have not yet received marketing authorization may be provided through national managed access programs.

On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of march-in rights, which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain whether that will continue under the new framework. It is unclear whether or how much such rights may be exercised.

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. presidential executive orders, congressional inquiries, and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. The IRA,

among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) 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 IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions took effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations. The prices of these ten drugs became effective January 1, 2026. On January 17, 2025, HHS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations by February 1, 2025. Weight loss drugs, including Ozempic, Rybelsus, and Wegovy, were chosen for the drug price negotiation. Negotiated prices for this second set of drugs will be effective starting January 1, 2027. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program.

The Trump Administration has stated that lowering the cost of prescription drugs for Americans is a top priority and it will continue to pursue drug price negotiations. There may be a significant impact on reimbursement for particular Part D drugs, including AOMs. We cannot predict how this might change or how any changes might impact our business.

Several pharmaceutical companies, as well as the U.S. Chamber of Commerce, and the Pharmaceutical Research and Manufacturers of America have filed lawsuits against HHS and CMS, asserting that, among other things, the IRA's drug price negotiation program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the U.S. Constitution and is otherwise unlawful. HHS has generally won the substantive disputes in these cases, and several federal district court judges have expressed skepticism regarding the merits of the legal arguments being pursued by the pharmaceutical industry. HHS has generally continued to win the substantive disputes in appeals, although certain cases continue to seek appellate review.

We expect that the ACA, the IRA, and any other healthcare reform measures that may be adopted in the future 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. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

The current Trump administration is pursuing policies to reduce regulations and expenditures across the government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions and proposals may, for example, include directives: (1) reducing agency workforce and cutting programs; (2) rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation, or CMNI, to consider new payment and healthcare models to limit drug spending; (3) eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan; (4) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (5) imposing tariffs on imported pharmaceutical products; and (6) directing certain federal agencies to enforce existing law regarding hospital and plan price transparency and by standardizing prices across hospitals and health plans. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved. Furthermore, on July 4, 2025, legislation commonly referred to as the One Big Beautiful Bill Act was signed into law, which reduced funding to federal healthcare programs and imposed additional requirements to be eligible for healthcare, which may result in decreased access to healthcare, particularly in Medicaid programs.

Further, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and the drug approval process. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or comparable foreign regulatory authorities more likely to terminate or suspend clinical trials before completion or require longer or additional clinical trials that may

result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Changing regulatory environments could negatively impact our business.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. 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. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Many European Economic Area (EEA) Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EEA Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EEA Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EEA Member States, including those representing the larger markets. The HTA process is the procedure to assess the therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EEA Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

In December 2021, Regulation No. 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the European Union. This Regulation, which entered into force in January 2022 and went into effect in January 2025, is intended to boost cooperation among EEA Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at European Union level for joint clinical assessments in these areas. The Regulation permits EEA Member States to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EEA Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EEA Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the European Union could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the European Union may continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of European Union and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

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

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of

trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government authorities or government-affiliated hospitals, universities, and other organizations.

We have engaged and will continue to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act (the FCPA), prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate and other related parties for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

If our procedures and controls to monitor anti-bribery compliance fail to protect us from reckless or criminal acts committed by our employees or agents or if we, or our employees, agents, contractors or other collaborators, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our research and development costs.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We, and the third parties with whom we share our facilities, are 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. Each of our operations involves the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations also produces 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. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

We cannot guarantee that the safety procedures utilized by our third-party manufacturers and CROs for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, nor can we eliminate the risk of accidental contamination or injury from these materials. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from hazardous materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, results of operations and financial condition.

Even if we commercialize any product candidates, alone or with our partners, any such product may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could adversely affect our business.

In some countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available products, which is time-consuming and costly. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. If coverage and reimbursement of our product candidates are unavailable or limited in scope or amount, our business could be materially harmed.

Risks Related to the Operation of Our Business

We have previously identified a material weakness in our internal control over financial reporting, which was subsequently remediated. If we experience additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

Prior to the completion of our IPO, we were a private company with limited accounting personnel to adequately execute our accounting processes and limited supervisory resources with which to address our internal control over financial reporting. In connection with the preparation of our consolidated financial statements for the year ended December 31, 2024, a material weakness was identified in the design and operating effectiveness of our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

As of December 31, 2025, we have remediated the previously identified material weakness in our internal control over financial reporting. See Part II, Item 9A, "Item 9A. Controls and Procedures", of our Annual Report on Form 10-K for the year ended December 31, 2025 for additional detail. However, our internal control over financial reporting may not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we identify additional material weaknesses or deficiencies in internal controls in the future and we are unable to correct them in a timely manner, our ability to record, process, summarize and report financial information accurately and within the time

periods specified in the rules and forms of the SEC, will be adversely affected. Any such failure could negatively affect the market price and trading liquidity of our common stock, lead to delisting, cause investors to lose confidence in our reported financial information, subject us to civil and criminal investigations and penalties, and generally materially and adversely impact our business and financial condition.

If, in the future, we identify material weaknesses in our internal controls over financial reporting or fail to meet the demands that are placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 of the Sarbanes-Oxley Act could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. If additional material weaknesses exist or are discovered in the future, and we are unable to remediate any such material weakness, our business, financial condition and results of operations could suffer.

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

We are highly dependent on our senior management team. The employment agreements we have with these officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. In addition, we will need to attract, retain and motivate highly qualified additional medical, scientific, technical, commercial, business, regulatory and administrative personnel. If we are not able to retain our management and to attract, on terms acceptable to us, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer operating history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to attract, retain and motivate high-quality personnel and consultants to accomplish our business objectives, the rate and success at which we can discover and develop product candidates and our business will be limited and we may experience constraints on our development objectives. Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future marketing approvals, sales of our product candidates and our results of operations.

There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel (including medical, scientific, technical, commercial, business, regulatory and administrative personnel) necessary to support our anticipated growth and develop our business. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among biotechnology businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We have in the past acquired, and may in the future acquire other assets, businesses or form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders’ ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets or licenses of assets, including preclinical, clinical or commercial stage products or product candidates, businesses, strategic alliances, joint ventures and collaborations, to expand our existing technologies and operations.

Any potential acquisition or strategic partnership may entail numerous risks, including:

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

In the future, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a negative impact on our cash flows, financial condition and results of operations. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could harm our financial condition and results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture.

To finance such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant amortization expense. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings or through the issuance of debt. Additional funds may not be available on terms that are favorable to us, or at all, and any debt financing may involve covenants limiting or restricting our ability to take certain actions.

We expect to expand our clinical development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of April 30, 2026, we had 40 employees and 35 full-time or part-time consultants. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, product development and manufacturing, regulatory affairs, quality assurance and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must:

- manage our preclinical studies and clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees, including additional clinical, manufacturing, regulatory, quality assurance, scientific development and sales personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities, to managing these growth activities. We currently have no marketing, sales or distribution capabilities. 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 ARD-101 or any other potential future product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources.

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

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize ARD-101 or any other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

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

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter 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 be in compliance 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 significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, 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 the curtailment or restructuring of our operations.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. For example, we have entered into agreements in which we agreed to indemnify an institution and related parties from any losses that may arise from claims relating to alleged infringement of intellectual property rights held by a third party and in which we agreed to indemnify a counterparty from third-party claims arising from the death of, injury to, or damage to property of any person resulting from the research, development or use of applicable rights or products under the agreement.

Should our obligation under an indemnification provision in any of our agreements exceed applicable insurance coverage or if we are denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if

we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Our ability to use our net operating loss (NOL) carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2025, we had federal NOL carryforwards of $79.3 million and state NOL carryforwards of $96.5 million. Under the Internal Revenue Code of 1986, as amended (the Code), our U.S. federal NOLs will not expire and may be carried forward indefinitely but the deductibility of U.S. federal NOLs is limited to no more than 80% of current year taxable income (with certain adjustments), and the state loss carryforwards begin expiring in 2037 unless previously utilized. In addition, under Sections 382 and 383 of 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 certain stockholders over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study; however, we have raised funds several times in recent years, increasing the likelihood there have been changes in ownership that would limit our ability to utilize tax attribute carryforwards. Furthermore, there may be additional ownership changes in the future or as a result of subsequent changes in our stock ownership, some of which may be outside of our control. As a result, if we undergo an ownership change, and our ability to use our pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes is limited, such an ownership change would harm our future results of operations by effectively increasing our future tax obligations. In addition, there is a risk that due to changes under the tax law, regulatory changes or other unforeseen reasons, our existing NOLs and other tax attributes could expire or otherwise be unavailable to offset future income tax liabilities. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Our operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire, earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are predominantly located in California. Any unplanned event, such as a flood, wildfire, explosion, earthquake, extreme weather condition, epidemic or pandemic, power outage, telecommunications failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party CMOs and CROs, could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage or other event occurred that prevented us from using our clinical sites, impacted clinical supply or the conduct of our clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and our CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. In the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance we currently carry will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs or CROs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

International expansion of our business will expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our business strategy contemplates international expansion, including partnering with distributors, and introducing our current products and other planned products outside the United States. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;

- potential failure by us or our distributors to obtain regulatory approvals for the sale or use of our current products and our planned future products in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing government payer systems, multiple payer-reimbursement regimes or self-pay systems;
- logistics and regulations associated with shipping products, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if our distributors do not execute successfully;
- financial risks, such as longer payment cycles, difficulties enforcing contracts and collecting accounts receivable, and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, including the outbreak of hostilities in Ukraine and Iran and other parts of the Middle East and potential destabilization in Venezuela, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the FCPA, including its books and records provisions and its anti-bribery provisions, by failing to maintain accurate information and control over sales activities and distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and consequently, have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We face an inherent risk of product liability exposure related to the testing of our current and future product candidates in clinical trials and may face an even greater risk if we commercialize any product candidate that we may develop. For example, we may be sued if any drug we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and breach of warranty. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- a diversion of management's time and our resources;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- substantial monetary awards paid to trial participants, subjects or patients;
- initiation of investigations by regulators;
- loss of revenue;
- a decline in our stock price; and
- the inability to commercialize any products that we may develop.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our 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 maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and

we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile and third-party, cloud-based technologies, to operate our business. In the ordinary course of our business, we may collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, and other confidential information. It is important that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our sensitive information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on or transmitted between those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external exploits of our technology environment. In addition, we may face increased risks of a security breach or disruption due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

Cyber incidents are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, supply chain attacks, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Data security incidents and other inappropriate access can also be difficult to detect, and any delay in identifying them may lead to increased harm. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of, or cyber incidents directed at, our or our third-party vendors’ and/or business partners’ information technology systems could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in a variety of adverse effects, including financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. If we or our third-party collaborators, consultants, contractors, suppliers, vendors or service providers were to suffer an actual or likely attack or breach, for example, that involves the unauthorized access to or use or disclosure of personal or health information, we may have to notify consumers, partners, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions (including mandatory corrective action or requirements to verify the correctness of database contents), and consuming, distracting and expensive litigation, any of which could result in increased costs to us, and result in significant legal and financial exposure, or other harm to our business and reputation.

While we have no reason to believe that we have been subject to any material system failure, accident or security breach to date, we have experienced cybersecurity incidents in the past and expect that we will experience cybersecurity incidents in the future. In addition, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. While we have implemented security measures intended to protect our information technology systems and infrastructure, such measures may not successfully prevent service interruptions or security incidents.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Failure to comply with data privacy and security laws, regulations and other obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, negative publicity, and/or other adverse consequences that could negatively affect our operating results and business.

We and our partners and vendors may be subject to federal and state privacy and data protection laws and regulations as well as international laws that impose broad compliance obligations on the collection, possession, use, storage, access, disclosure, transfer, deletion and protection of personal data. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal data, could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to penalties if we violate HIPAA. HIPAA mandates the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Requirements for compliance under HIPAA are also subject to change, as the U.S. Department of Health and Human Services Office of Civil Rights issued a proposed rule that would amend certain security compliance requirements for covered entities and business associates.

Even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal data secure may constitute unfair acts or practices in or affecting commerce in violation of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of personal data it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. Additionally, the FTC Health Breach Notification Rule applies to health apps and other similar technologies and expanded breach notification requirements, which adds complexity to compliance obligations. Further, the SEC implemented rules around incident reporting, requiring cybersecurity incidents to be reported 4 business days after determining that an incident is material.

The U.S. Department of Justice issued a final rule entitled, "Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," codified at 28 CFR part 202, or the Bulk Transfer Rule. The Bulk Transfer Rule prohibits and restricts bulk transfers of sensitive personal data (including genetic and health data) to countries of concern, such as China, Russia, and Iran to prevent access by foreign adversaries. It restricts our ability to engage in certain cross-border transactions involving genomic or biological samples and related data, which may increase compliance costs, lead to increased regulatory scrutiny or liability, and may require additional contractual negotiations, which may adversely impact our business, financial condition, and operating results.

Certain state laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to protected health information than HIPAA, many of which may differ from each other, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the California Consumer Privacy Act (CCPA), revised and amended by the California Privacy Rights Act (CPRA), created new individual privacy rights for California residents, including the right to opt out of certain disclosures of their data, the right to limit the use and disclosure of sensitive personal information (including health information). The CCPA places increased privacy and security obligations on entities handling certain personal data of California residents or households, limits data use and mandates audit requirements for higher risk data. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although there are limited exemptions for clinical trial data and some other health data under the CCPA, as currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and PHI. The CCPA is enforced by the California Privacy Protection Agency, a data protection authority, which has the power to issue substantive regulations resulting in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required.

While California was the first among the states to adopt comprehensive data privacy legislation similar to the GDPR, many other states are following suit, which could increase our potential liability and adversely affect our business. More than 20 states have adopted statewide comprehensive privacy laws and many other states have privacy legislation that is pending. Many of these new state laws contain some type of exemption for information collected under HIPAA and some data processed in the context of clinical trials, either at the entity level or the data level, so the impact might be limited particularly as it relates to PHI. Some states also have laws that specifically focus on the processing of personal data related to individuals' health, including California's Confidentiality of

Medical Information Act and Washington's My Health My Data Act. Changes to federal and state privacy laws may add complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would 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 non-compliance.

In addition, all 50 U.S. states and territories and international jurisdictions have varying breach notification laws that may require us to notify patients, employees or regulators in the event of unauthorized access to or disclosure of personal or confidential data experienced by us or our service providers. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. We also may be contractually required to notify patients or other counterparties of a security breach. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards.

Foreign data protection laws, including the European Union's General Data Protection Regulation (the EU GDPR), and the United Kingdom's equivalent of the same (the UK GDPR), may also apply to our processing of health-related and other personal data regardless of where the processing in question is carried out.

The GDPR in the EEA and the UK GDPR in the United Kingdom (together, the GDPR) impose stringent requirements for controllers and processors of personal data of individuals within the EEA or the United Kingdom. The GDPR applies to any company established in the EEA or United Kingdom as well as to those outside the EEA or United Kingdom if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or United Kingdom or the monitoring of their behavior. The GDPR, together with national legislation, regulations and guidelines of the EEA Member States and the United Kingdom governing the processing of personal data, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for non-compliance of up to €20 million (£17.5 million) or 4% of the annual global revenues of the non-compliant company, whichever is greater. Such requirements may be subject to change in the near future as the European Commission announced proposed amendments to the GDPR in November 2025. In addition, on June 19, 2025, the UK's Data (Use and Access) Act 2025, or the DUAA, was granted Royal Assent, implementing various measures concerning data usage in the UK and reforming data protection laws. It remains too soon to tell how the DUAA will be implemented and what impact it will have on our international activities. Further, other EU and member state laws and regulations may impose further obligations or restrictions on processing health information in the EEA, such as the European Health Data Space Regulation.

In the EEA, the NIS 2 Directive, or NIS 2, is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. NIS 2 brings new medium and large organizations providing services in the EEA within scope of the legal framework. It extends to additional sectors and expands the list of in-scope healthcare organizations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization's compliance with NIS 2, requires covered organizations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with greater oversight. The majority of obligations will come into force when national legislation implementing NIS 2 becomes effective in the relevant EU Member State. EU Member States had until October 17, 2024 to transpose NIS 2 into national legislation, although many countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EU is currently fragmented and uncertain. To the extent that we become subject to NIS 2 in the future, we may require additional investment of our resources in compliance programs. Under NIS 2, companies may be subject to administrative fines of up to the higher amount of €10 million or 2% of worldwide turnover.

Certain jurisdictions, including the EEA, have enacted laws and regulations governing cross-border personal information transfer and providing for data localization in certain cases. For example, absent appropriate safeguards or other circumstances, the GDPR and laws in Switzerland and the UK generally restrict the transfer of personal information to countries outside the EEA, Switzerland and the UK, such as the United States. Such safeguards include the use of standard contractual clauses approved by the European Commission and the UK and Swiss Data Protection Authorities as well as the EU-U.S. Data Privacy Framework. If we are unable to implement a valid solution to transfer personal data from the EEA to the United States or other countries that have not been deemed to provide an essentially equivalent level of data protection, we may face increased exposure to regulatory action, substantial fines, or injunction orders to stop processing personal data from EEA, Swiss, or UK residents. Any inability to import personal data to

the United States may also restrict our clinical trials activities in the EU; limit our ability to collaborate with CROs as well as other service providers, contractors and other companies subject to EU data privacy and security laws; and require us to increase our data processing capabilities in the EU and the UK at a significant expense. Additionally, other countries outside of the EU have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. The types of challenges we face in the EEA, Switzerland, and the UK will likely also arise in other jurisdictions that adopt laws similar to the GDPR or regulatory frameworks of equivalent complexity.

Implementing mechanisms to endeavor to ensure compliance with the GDPR and relevant local legislation in EEA Member States and the United Kingdom may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations, and prospects. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, and orders to cease/change our use of data, enforcement notices, or potential civil claims including class-action-type litigation. While we have taken steps to comply with the GDPR where applicable, including by reviewing our security procedures, engaging data protection personnel, and entering into data processing agreements with relevant contractors, our efforts to achieve and remain in compliance may not be fully successful.

Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or, in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could adversely affect our business, operating results, prospects or financial condition.

Risks Related to Artificial Intelligence

We may use certain artificial intelligence (AI) technologies, which present risks and challenges that could adversely impact our business. As with many innovations, ineffective or inadequate AI development or deployment practices could result in unintended consequences. For example, AI algorithms we use in connection with our operations may be flawed or based on datasets that are biased or insufficient, potentially leading to errors in our business processes. Disruption or failure in AI functionality could adversely affect our business, cause delays or inaccuracies in our offerings, or harm our reputation. Conversely, if we are unable to adopt and deploy AI effectively as quickly as our competitors, it may cause us to be relatively less productive or innovative, adversely impacting our competitiveness and requiring additional investments that increase our costs. AI technologies may increase cybersecurity, privacy and data protection risks, including the risk that employees, contractors or vendors inadvertently input, expose, or enable access to confidential, proprietary, or regulated information through AI tools or related integrations. In addition, AI systems may be vulnerable to novel attacks (such as prompt injection or data poisoning) and, if we deploy AI-enabled automation or systems that can take actions based on AI outputs, those systems could execute unintended, unauthorized, or harmful actions due to inaccurate, manipulated, or improperly reviewed outputs. Laws and regulations regarding AI technologies are rapidly evolving as well, including in the areas of intellectual property, cybersecurity, privacy and data protection. Compliance with new or changing laws, regulations, or industry standards relating to AI may impose significant operational and financial burdens and may limit our ability to develop, deploy, or use AI technologies in our business.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receive regulatory approval, they 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.

If any of our product candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue 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 but not limited to:

- the clinical indications for which the product candidate is approved;
- the efficacy, safety and potential advantages compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;

- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments and products;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling requirements of the FDA or comparable foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning or patient inserts;
- the availability of the approved product candidate for use as a combination therapy;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force in the United States;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our product candidates, once approved;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications (e.g., contraindications).

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates, if approved, to find market acceptance, could adversely affect our business and could require us to seek additional financing.

If we are unable to establish sales, marketing and distribution capabilities for our product candidates that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We have no internal sales, marketing or distribution capabilities, nor have we as a company commercialized a product. If any of our product candidates ultimately receives marketing approval, we will be required to build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in the markets that we target, which will be expensive and time-consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of establishing our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these product candidates. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- 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.

If we are unable to establish our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we are not successful in commercializing our product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses, which could adversely affect our business, operating results, prospects or financial condition.

We face substantial competition, which may result in a smaller than expected commercial opportunity and/or others discovering, developing or commercializing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. We face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

If any of our product candidates are approved for the indications for which we expect to conduct clinical trials, we anticipate they will compete with the foregoing therapies and currently marketed drugs, as well as any drugs potentially in development. It is also possible that we will face competition from other pharmaceutical approaches as well as other types of therapies. The key competitive factors affecting the success of all our programs, if approved, are likely to be their potency, tolerability, convenience, price, level of generic competition, and availability of reimbursement.

With respect to ARD-101, Soleno Therapeutics' (Soleno) VYKAT XR is the only approved treatment for PWS-associated hyperphagia. On April 6, 2026, Soleno announced that it entered into a definitive agreement for Neurocrine Biosciences, Inc. to acquire Soleno for $53.00 per share in cash, and we believe this acquisition of Soleno, if completed, may have the potential to accelerate the commercialization of VKKAT XR as Soleno will become part of a larger organization with increased access to capital and broader commercialization capabilities. We are also aware of therapeutic candidates in development programs with reported hyperphagia reducing activity in patients with PWS, including those from Rhythm Pharmaceuticals, Relmada Therapeutics and Bright Minds Biosciences Inc.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that have fewer or less severe side effects, are more potent, are more convenient, are less expensive or are sold more effectively than any products that we may develop. Our competitors also may obtain FDA or other applicable regulatory authority approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of any product candidates we develop, if approved, could be adversely affected.

The success of our product candidates will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these products.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Assuming we obtain coverage for our product candidates by a

third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EEA or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated.

An increasing number of third-party payors are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive product is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive drug. Even if we show more favorable efficacy or a more favorable convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because higher prices are often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved, and may not be able to obtain a satisfactory financial return on our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures within the United States, could further limit our net revenue and results. The IRA, for example, includes provisions that impose new manufacturer financial liability on certain drugs under Medicare Part D, allowing the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition. Orphan drugs are exempted from the Medicare drug price negotiation program, but as described in CMS guidance, this exemption will apply only to products that have no more than one rare disease designation and for which the only approved indication is for that disease or condition. Decreases in third-party reimbursement for our drug product candidate or a decision by a third-party payor to not cover our drug product candidate could reduce physician usage of the drug product candidate and have a material adverse effect on our sales, results of operations and financial condition.

Moreover, increasing efforts by governmental and 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. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

There can be no assurance that our product candidates, if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary, that it will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the United States and in other countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale.

If the market opportunities for any of our product candidates are smaller than we estimate, even assuming approval of a product candidate, our revenue may be adversely affected, and our business may suffer.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new information may change the estimated incidence or prevalence of these diseases. For example, PWS is a rare disease, and as such, our projections of both the number of people who have this disease, as well as the subset of people with PWS who have the potential to benefit from treatment with our product candidate, are based on estimates. Currently, most reported estimates of the prevalence of PWS are based on studies of small subsets of the population of specific geographic areas, which are then extrapolated to estimate the prevalence of the disease in the broader world population. There can be no assurance that the prevalence of PWS in the study populations, particularly in these newer studies, accurately reflects the prevalence of this disease in the broader world population. If our estimates of the prevalence of PWS or of the number of patients who may benefit from treatment with our product candidates prove to be incorrect, the market opportunities for our product candidate may be smaller than we believe it is, our prospects for generating revenue may be adversely affected and our business may suffer.

The total addressable market across our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Risks Related to Ownership of Our Common Stock and Our Status as a Public Company

An active and liquid trading market for our common stock may not develop and you may not be able to resell your shares of common stock at or above the public offering price, if at all.

Our common stock has traded on the Nasdaq Global Select Market under the symbol "AARD" since February 13, 2025. We can provide no assurance that a more active or liquid trading market for our common stock will develop or be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

****Our stock price may be volatile, which could result in substantial losses for investors purchasing shares of our common stock.***

The market price of our common stock is volatile and could fluctuate widely in response to many factors, including but not limited to:

- volatility and instability in the financial and capital markets;

- announcements relating to our product candidates, including the results of clinical trials by us or our collaborators;
- announcements by competitors that impact our competitive outlook;
- negative developments with respect to our product candidates, or similar products or product candidates with which we compete;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to pause or terminate an existing clinical trial;
- developments with respect to patents or intellectual property rights;
- announcements of technological innovations, new product candidates, new products or new contracts by us or our competitors;
- announcements relating to strategic transactions, including acquisitions, collaborations, licenses or similar arrangements;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by equities research analysts and whether our earnings (or losses) meet or exceed such estimates;
- announcement or expectation of additional financing efforts and receipt, or lack of receipt, of funding in support of conducting our business;
- sales of our common stock by us, our insiders, or other stockholders, or issuances by us of shares of our common stock in connection with strategic transactions;
- conditions and trends in the pharmaceutical, biotechnology and other industries;
- regulatory developments within, and outside of, the United States, including changes in the structure of healthcare payment systems;
- litigation or arbitration;
- pandemics, natural disasters or major catastrophic events;
- general economic, political and market conditions, acts of war or terrorism, such as the conflicts involving Ukraine and Russia, or Israel and its surrounding regions, and other factors; and
- the occurrence of any of the risks described in Part I, Item 1A, “Risk Factors,” of our Annual Report on Form 10-K for the year ended December 31, 2025.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

Since our IPO, we have experienced volatility in our stock price. For example, from February 13, 2025 (the date our common stock commenced trading on the Nasdaq Global Select Market) to April 30, 2026, our closing stock price ranged from $3.51 to $17.41 per share. In particular, following our announcement in February 2026 that we have voluntarily paused enrollment and dosing in the Phase 3 HERO trial and the OLE trial for ARD-101, and the POWER and STRENGTH clinical trials for ARD-201 based on reversible cardiac observations in a healthy volunteer study of ARD-101, the trading price of our common stock declined significantly, closing at $12.49 per share prior to the announcement on February 27, 2026 and then closing at $5.47 per share on March 2, 2026, the next trading day thereafter. When the market price of a stock has been volatile, as our stock price has been, holders of that stock have occasionally brought securities class action litigation claims against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit were without merit, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly and annual fluctuations which may, in turn, cause the price of our common stock to fluctuate significantly. Our net loss and other operating results will be affected by numerous factors, including:

- the timing and cost of, and level of investment in, research, development, pre-commercial and, if approved, commercialization activities relating to our product candidates, which may change from time to time;

- the timing and status of enrollment for our 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;
- the timing of payments we may make or receive under existing license and collaboration arrangements or the termination or modification thereof;
- our execution of any strategic transactions, including acquisitions, collaborations, licenses or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions;
- 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;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- recruitment and departures of key personnel;
- the timing of receipt of approvals for, and the scope of or limitation on the marketing authorizations received on, our product candidates from regulatory authorities in the United States and internationally;
- coverage and reimbursement policies with respect to our product candidates, if approved, and currently approved products or potential future drugs that compete or may compete with our product candidates;
- the level of demand for our product candidates, if approved, which may vary significantly over time;
- regulatory developments affecting our product candidates or those of our competitors;
- fluctuations in stock-based compensation expense;
- the impacts of inflation and rising interest rates on our business and operations; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Because we do not anticipate paying any dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared nor paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and we do not anticipate declaring or paying any dividends in the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. As a result, capital appreciation of our common stock, which may never occur, will be your sole source of gain on your investment for the foreseeable future.

Our board of directors is authorized to issue and designate shares of our preferred stock without stockholder approval.

Our Fourth Amended and Restated Certificate of Incorporation, as may be amended from time to time (Certificate of Incorporation), authorizes our board of directors, without the approval of our stockholders, to issue shares of preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our Certificate of Incorporation, and to establish from time to time the number of shares of preferred stock to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of convertible preferred stock may be senior to or on parity with our common stock, which may reduce our common stock's value.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested.

****Our principal stockholders and management own a significant percentage of our common stock and are able to control matters subject to stockholder approval.***

As of April 30, 2026, our executive officers, directors and holders of 5% or more of our capital stock beneficially owned approximately 52.3% of the outstanding shares of our common stock. As a result, such stockholders, acting together, have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, amendments of our organizational documents, the election and removal of directors and approval of any major corporate transactions, as well as our management and business affairs. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay, defer or prevent a change of control of our company, impede a merger, consolidation, takeover or other business combination involving us, or discourage a potential acquirer from making a tender offer or otherwise attempt to obtain control of our business, even if such a transaction would benefit our other stockholders. This 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.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us that may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our Certificate of Incorporation and Amended and Restated Bylaws (Bylaws) contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a staggered board of directors divided into three classes serving staggered three-year terms, such that not all members of our board of directors will be elected at one time;
- authorize our board of directors to issue one or more new series of preferred stock without stockholder approval and create, subject to applicable law, one or more series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- eliminate the ability of our stockholders to fill vacancies on our board of directors;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;
- permit our board of directors to establish the number of directors;
- provide that our board of directors is expressly authorized to make, alter or repeal our Bylaws;
- provide that stockholders can remove directors only for cause and only upon the approval of not less than 66-2/3% of all outstanding shares of our capital stock;
- require the approval of not less than 66-2/3% of all outstanding shares of our capital stock to amend the Bylaws and specific provisions of the Certificate of Incorporation; and
- specify the jurisdictions in which certain stockholder litigation may be brought.

In addition, because we are incorporated in Delaware, we are governed by Section 203 of General Corporation Law of the State of Delaware (the DGCL), which may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock, unless the holder has held the stock for three years or, among other exceptions, our board of directors has approved the transaction. Any of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock, and they could deter potential acquirers of our company, thereby reducing the likelihood the holders of our common stock would receive a premium for their shares of our common stock in an acquisition.

The Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Certificate of Incorporation, to the fullest extent permitted by law, provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction) shall be the sole and exclusive forum, in all cases subject to the court's having jurisdiction over indispensable parties named as defendants, for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty owed to us or our stockholders by any director, officer or other employee; (iii) any action asserting a claim against us or any director, officer or other employee arising pursuant to the DGCL; (iv) any action to interpret, apply, enforce or determine the validity of the Certificate of Incorporation or the Bylaws; or (v) any other action asserting a claim that is governed by the internal affairs doctrine. In addition, the Certificate of Incorporation provides that the federal district courts of the United States are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the exclusive forum provision does not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may result in increased costs to stockholders to bring a claim for any such dispute and may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in the Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, operating results, prospects or financial condition. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

General Risk Factors

Recent and future changes to tax laws could materially adversely affect our company.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, and the IRA enacted many significant changes to the U.S. tax laws. Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. For example, the IRA includes provisions that will impact the U.S. federal income taxation of certain corporations, including imposing a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. On July 4, 2025, legislation commonly referred to as the One Big Beautiful Bill Act was signed into law and extended many of the tax law provisions that were set to expire in 2025. Further changes to the tax laws or changes to the administrative or judicial interpretations of such laws are possible and may apply with retroactive effect. In addition, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission), have proposed, recommended, or (in the case of countries) enacted or otherwise become subject to changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business.

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

We may be the target of securities litigation in the future, including based on volatility in the market price of our stock. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. The market price of our common stock is volatile. For example, following our announcement in February 2026 that we have voluntarily paused enrollment and dosing in the Phase 3 HERO trial and the OLE trial for ARD-101, and the POWER and STRENGTH clinical trials for ARD-201 based on reversible cardiac observations in a healthy volunteer study of ARD-101, the trading price of our common stock declined significantly, closing at $12.49 per share prior to the announcement on February 27, 2026 and then closing at $5.47 per share on March 2, 2026, the next trading day thereafter. In the past, companies that have experienced volatility and/or declines in the market price of their stock have been subject to securities class action litigation. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from any such proceeding) can be expensive, time-consuming, damage our reputation and

divert our management's and board of directors' attention from other business concerns, which could adversely affect our business, operating results, prospects or financial condition.

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

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, Nasdaq listing requirements, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Exchange Act currently requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We may plan to hire additional support for financial reporting and internal controls and other finance personnel or consultants in order to improve and implement appropriate internal controls and reporting procedures, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations and prospects may be significantly harmed.

The future issuance of equity or of debt securities that are convertible into equity would dilute our share capital.

We may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. To the extent that additional capital is raised through the issuance of shares or other securities convertible into shares, our stockholders will be diluted. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or other equity securities or the availability of common stock for future sales will have on the trading price of our common stock.

Pursuant to our 2025 Equity Incentive Plan (2025 Plan), our management is authorized to grant equity awards to our employees, directors and consultants. Initially, the aggregate number of shares of our common stock that may be issued pursuant to equity awards under the 2025 Plan was 2,150,000 shares, which was automatically increased by 1,090,767 shares effective January 1, 2026. Additionally, the number of shares of our common stock reserved for issuance under the 2025 Plan will automatically increase on January 1st of each year, continuing through and including January 1, 2035, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Further, in May 2025, the Compensation Committee of the board of directors (the Compensation Committee) approved the Company's 2025 Inducement Equity Incentive Plan (the 2025 Inducement Plan) and reserved 900,000 shares of common stock for issuance thereby. If the board of directors or Compensation Committee approves issuances under the 2025 Inducement Plan, our stockholders may experience additional dilution, which could cause our stock price to fall.

****Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.***

On March 23, 2026, we filed a shelf Registration Statement on Form S-3 (File No. 333-294537) that became effective on April 3, 2026, which allows us to undertake various equity and debt offerings up to $400.0 million. In addition, on March 23, 2026, we

entered into an Equity Distribution Agreement with the Agent, pursuant to which we may offer and sell from time to time through the Agent up to $150.0 million in shares of our common stock. As of March 31, 2026, we have not sold any shares of common stock under the ATM Facility.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity or equity-linked securities.

The 747,870 shares of our common stock that are subject to outstanding options under the 2017 Equity Incentive Plan (2017 Plan) as of March 31, 2026 became eligible for sale in the public market after our IPO, to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of our common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of 5,710,444 shares of our outstanding common stock, or approximately 26.2% of our total outstanding common stock as of April 30, 2026, are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could adversely affect the trading price of our common stock.

Techniques employed by short sellers may drive down the market price of our common stock.

Short selling is the practice of selling securities that the seller does not own, but rather has borrowed from a third-party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller's best interests for the price of the stock to decline, many short sellers publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects in order to create negative market momentum and generate profits for themselves after selling a stock short. These short attacks have, in the past, led to selling of shares in the market. While we would strongly defend against any such short seller attacks, we may be constrained in the manner in which we can proceed against the relevant short seller by applicable state law or issues of commercial confidentiality. Such a situation could be costly and time-consuming, and could be distracting for our management team. Additionally, such allegations against us could negatively impact our business operations and stockholders' equity, and the value of any investment in our stock could be reduced.

We are 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 JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements. We have taken advantage of these reduced reporting burdens in our periodic reports. 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. Even after we no longer qualify as an emerging growth company, we could still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

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 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 are not 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 are able to take advantage of these scaled disclosures for so long as our 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.

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

The trading market for our common stock may be influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or if analysts cease coverage of us, we could lose visibility in the financial markets, and the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

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

Our business is susceptible to general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn, including a recession or depression resulting from the political disruption, could result in a variety of risks to our business, including weakened demand for our current or future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential drugs, if approved. The ongoing conflict between Russia and Ukraine and sanctions against Russia are causing disruptions to global economic conditions. The ongoing conflicts in the Middle East, including the war in Iran and its surrounding regions, and instability in Venezuela are also causing disruptions to global economic conditions. Further, in recent years the global equity markets in general have experienced extreme price and volume fluctuations, including as a result of economic uncertainty and increased interest rates, inflation, the government closure of Silicon Valley Bank and Signature Bank, and liquidity concerns at other financial institutions that may be unrelated to our operating performance. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

Furthermore, the current U.S. administration has substantially departed from prior U.S. government international trade policy and has commenced activities to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements and treaties with foreign countries. In addition, the current U.S. administration has initiated and is considering imposing additional tariffs on certain foreign goods. Related to this action, certain foreign governments, including China, have instituted or are considering imposing reciprocal tariffs on certain U.S. goods. It remains unclear what the current U.S. administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers,

increase the cost of materials purchased to manufacture our product candidates and negatively impact the United States or global economy or certain sectors thereof and, thus, could adversely impact our business, financial condition or results of operations.

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

(a) Unregistered Sales of Equity Securities

None.

(b) Use of Proceeds

On February 12, 2025, our registration statement on Form S-1 (File No. 333-284440) for our IPO was declared effective by the SEC. There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on February 13, 2025. As of March 31, 2026, we estimate that we have used approximately $65.3 million of the proceeds from our IPO for general corporate purposes, including to fund the clinical development of ARD-101 and our other clinical and preclinical activities, as well as operating expenses. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities, or to any of our affiliates

(c) Issuer Repurchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Arrangements

From time to time, our officers (as defined in Rule 16a–1(f)) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the quarter ended March 31, 2026, none of our officers or directors adopted or terminated any such trading arrangements.

Item 6. Exhibits

Exhibit Number	Description of Document
3.1	Fourth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of our Current Report on Form 8-K (File No. 001-42513), filed on February 14, 2025).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 of Amendment No. 1 of our Registration Statement on Form S-1/A (File No. 333-284440), filed on February 6, 2025).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 of Amendment No. 1 of our Registration Statement on Form S-1/A (File No. 333-284440), filed on February 6, 2025).
10.1+	Letter Agreement, dated February 9, 2026, between the Company and Bryan Jones, Ph.D. (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-42513), filed on February 12, 2026).
10.2	Equity Distribution Agreement, dated as of March 23, 2026, by and between Aardvark Therapeutics, Inc. and Piper Sandler & Co. (incorporated by reference to Exhibit 1.2 to the Registration Statement on Form S-3 (File No. 333-294537) filed by the Company on March 23, 2026).
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1†	Certification of the 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 the 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 management contract or compensatory plan.

† Furnished herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

AARDVARK THERAPEUTICS, INC.

Date: May 7, 2026

By: /s/ Tien-Li Lee, M.D.
Tien-Li Lee, M.D.
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Nelson Sun
Nelson Sun
Chief Financial Officer and Chief Operating Officer
(Principal Financial and 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, Tien-Li Lee, M.D., certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 7, 2026

By: /s/ Tien-Li Lee, M.D.
Tien-Li Lee, M.D.
Chief Executive Officer
(Principal Executive Officer)

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, Nelson Sun, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 7, 2026

By: /s/ Nelson Sun

Nelson Sun
Chief Financial Officer
(Principal 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 Aardvark Therapeutics, Inc. (the "Company") for the quarter ended March 31, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: May 7, 2026

By: /s/ Tien-Li Lee, M.D.
Tien-Li Lee, M.D.
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report, is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

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 Aardvark Therapeutics, Inc. (the "Company") for the quarter ended March 31, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: May 7, 2026

By: /s/ Nelson Sun
Nelson Sun
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report, is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.