UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended 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: 001-40656

TENAYA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**81-3789973**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
171 Oyster Point Boulevard, Suite 500 South San Francisco, CA	**94080**
(Address of principal executive offices)	**(Zip Code)**

(650) 825-6990
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

As of May 1, 2026, the registrant had 216,998,876 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (Quarterly Report), contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). 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, development plans, planned preclinical studies and clinical trials, future results of clinical trials, expected research and development costs, regulatory strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, investors can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. These forward-looking statements include, but are not limited to, statements about:

- our vision to change the treatment paradigm for heart disease;
- the ability of our ongoing preclinical studies and ongoing or planned clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing, dosing, patient enrollment and populations, progress, and results of preclinical studies and ongoing or planned clinical trials for our current product candidates and other product candidates we may develop;
- the timing, scope and likelihood of regulatory filings, approvals, and alignment, including timing of investigational new drugs (INDs), clinical trial applications (CTAs), U.S. Food and Drug Administration (FDA) approvals, and final regulatory approval of our current product candidates and any other future product candidates;
- our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical trials;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- our competitive position, potential advantages of our products compared to our competitors, and the success of competing therapies that are or may become available;
- our plans relating to the further development of our product candidates, including additional indications and targets we may pursue, and our belief in the potential applications of our current product candidates to additional indications and targets;
- our collaboration with Alnylam, including potential targets, research and development strategy, the timing and duration of the collaboration, expected payments, and the achievement of milestones;
- the impact of existing laws and regulations and regulatory developments in the United States (U.S.), Europe and other jurisdictions;
- our intellectual property position, including the scope and length of protection we are able to establish and maintain for intellectual property rights covering our current product candidates and other product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our continued reliance on third parties to conduct additional preclinical studies and clinical trials of our product candidates, and for the development and manufacture of our product candidates for preclinical studies and clinical trials;
- our ability to obtain, and negotiate favorable terms of, any collaboration, partnership, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;

- the pricing and reimbursement of our current product candidates and other product candidates we may develop, if approved, including any increase in demand as a result of the availability of reimbursement from the government and third-party payors;
- the rate and degree of market acceptance and clinical utility of our current product candidates and other product candidates we may develop;
- our estimates regarding expenses, operating losses, future revenue, cash outlays, capital requirements and needs for additional financing, including expenses arising as a result of being a public company;
- our financial performance;
- our facilities;
- the period over which we estimate our existing cash, cash equivalents and investments in marketable securities will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of critical accounting policies on investors' ability to understand our financial performance; and
- our expectations regarding the period during which we will remain an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (JOBS Act).

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Quarterly Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, investors should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

In addition, statements such as "we believe" and similar 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 investors are cautioned not to unduly rely upon these statements.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

TENAYA THERAPEUTICS, INC.

Condensed Balance Sheets
(In thousands)
(Unaudited)

	March 31, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 80,887	$ 100,547
Accounts receivable	10,627	—
Prepaid expenses and other current assets	5,048	5,039
Total current assets	96,562	105,586
Property and equipment, net	25,960	27,672
Operating lease right-of-use assets	8,763	9,417
Other noncurrent assets	3,785	4,246
Total assets	$ 135,070	$ 146,921
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,914	$ 3,581
Accrued and other current liabilities	6,030	8,835
Contract liabilities, current	5,722	—
Operating lease liabilities, current	3,115	3,020
Total current liabilities	16,781	15,436
Contract liabilities, noncurrent	4,680	—
Operating lease liabilities, noncurrent	7,002	7,810
Other noncurrent liabilities	418	410
Total liabilities	28,881	23,656
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 200,000,000 shares authorized as of March 31, 2026 and December 31, 2025; no shares issued and outstanding as of March 31, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized as of March 31, 2026 and December 31, 2025; 216,998,876 and 216,760,283 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	21	21
Additional paid-in capital	730,448	728,252
Accumulated other comprehensive income (loss)	—	—
Accumulated deficit	(624,280)	(605,008)
Total stockholders' equity	106,189	123,265
Total liabilities and stockholders' equity	$ 135,070	$ 146,921

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

TENAYA THERAPEUTICS, INC.

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

	Three Months Ended March 31,	
	2026	**2025**
Revenue		
Collaboration revenue	$ 225	$ —
Operating expenses:		
Research and development	14,843	21,076
General and administrative	5,447	6,462
Total operating expenses	20,290	27,538
Loss from operations	(20,065)	(27,538)
Other income, net:		
Interest income	793	635
Other income, net	—	39
Total other income, net	793	674
Net loss before income tax expense	(19,272)	(26,864)
Income tax expense	—	—
Net loss	(19,272)	(26,864)
Other comprehensive loss		
Net unrealized loss on marketable securities	—	(38)
Comprehensive loss	$ (19,272)	$ (26,902)
Net loss per share, basic and diluted	$ (0.09)	$ (0.24)
Weighted-average shares used in computing net loss per share, basic and diluted	216,883,164	109,869,278

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

TENAYA THERAPEUTICS, INC.

Condensed Statements of Stockholders' Equity
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of January 1, 2026	216,760,283	$ 21	$ 728,252	$ —	$ (605,008)	$ 123,265
Issuance of common stock upon vesting of restricted stock units	238,593	—	—	—	—	—
Stock-based compensation	—	—	2,196	—	—	2,196
Other comprehensive loss	—	—	—	—	—	—
Net loss	—	—	—		(19,272)	(19,272)
Balance as of March 31, 2026	216,998,876	$ 21	$ 730,448	$ —	$ (624,280)	$ 106,189

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of January 1, 2025	86,542,340	$ 8	$ 607,229	$ 28	$ (514,411)	$ 92,854
Issuance of common stock and warrants in follow-on offering, net of issuance costs of $3,699	75,000,000	8	48,793	—	—	48,801
Issuance of common stock upon vesting of restricted stock units	295,191	—	—	—	—	—
Issuance of common stock in connection with at-the market sales, net of issuance costs of $280	822,566	—	912	—	—	912
Stock-based compensation	—	—	3,731	—	—	3,731
Other comprehensive loss	—	—	—	(38)	—	(38)
Net loss	—	—	—		(26,864)	(26,864)
Balance as of March 31, 2025	162,660,097	$ 16	$ 660,665	$ (10)	$ (541,275)	$ 119,396

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

TENAYA THERAPEUTICS, INC.

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

	Three Months Ended March 31,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (19,272)	$ (26,864)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,763	2,661
Amortization (accretion) of premium (discount) on marketable securities	—	31
Stock-based compensation	2,196	3,731
Non-cash operating lease expense	654	596
Other	8	168
Changes in operating assets and liabilities:		
Accounts receivable	(10,627)	—
Prepaid expenses and other current assets	(9)	(460)
Other noncurrent assets	461	4
Accounts payable	(1,460)	(379)
Accrued and other current liabilities	(2,637)	(1,903)
Contract liabilities	10,402	—
Operating lease liabilities	(713)	(697)
Net cash used in operating activities	(19,234)	(23,112)
Cash flows from investing activities:		
Purchases of property and equipment	(11)	(383)
Proceeds from sales of marketable securities	—	10,958
Proceeds from maturities of marketable securities	—	11,727
Net cash (used) provided by investing activities	(11)	22,302
Cash flows from financing activities:		
Proceeds from issuance of common stock, pre-funded warrants, and warrants in follow-on offering, net of issuance costs	—	49,345
Proceeds from at-the-market sales, net of issuance costs	—	914
Payment of accrued offering costs	(415)	—
Net cash (used) provided by financing activities	(415)	50,259
Net change in cash, cash equivalents and restricted cash	(19,660)	49,449
Cash and cash equivalents and restricted cash at beginning of period	100,966	4,742
Cash and cash equivalents and restricted cash at end of period	$ 81,306	$ 54,191
Components of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 80,887	$ 53,772
Restricted cash included in other noncurrent assets	419	419
Cash, cash equivalents and restricted cash	$ 81,306	$ 54,191
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment included in accounts payable and accrued and other current liabilities	$ 100	$ 138
Offering cost included in accounts payable and accrued expenses and other current liabilities	$ —	$ 546

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

TENAYA THERAPEUTICS, INC.

Notes to Unaudited Condensed Financial Statements

1. Organization and Description of the Business

Description of the Business

Tenaya Therapeutics, Inc. (the Company) was incorporated in the state of Delaware in August 2016 and is headquartered in South San Francisco, California. The Company is a clinical-stage biotechnology company focused on discovering, developing and delivering curative therapies that address the underlying drivers of heart disease. The Company's lead product candidates include TN-201, a gene therapy for myosin binding protein C3-associated hypertrophic cardiomyopathy, TN-401, a gene therapy for plakophilin 2-associated arrhythmogenic right ventricular cardiomyopathy, and TN-301, a small molecule with potential clinical utility in cardiac, metabolic and muscular conditions, including heart failure with preserved ejection fraction and Duchenne's muscular dystrophy.

Liquidity

The Company has incurred net losses since inception and expects such losses to continue in the future as it conducts research and development activities. As of March 31, 2026, the Company had an accumulated deficit of $624.3 million. The Company incurred a net loss of $19.3 million and $26.9 million during the three months ended March 31, 2026 and 2025, respectively. The Company had $80.9 million of cash and cash equivalents as of March 31, 2026.

Management recognizes the need to raise additional capital to fully implement its business plan. The Company may seek to raise capital through equity financings, debt financings, license agreements, collaborative agreements or other sources of financing. Management believes that its existing cash and cash equivalents as of March 31, 2026, will be sufficient to fund the Company's operations for at least the next twelve months following the date these financial statements are filed with the Securities and Exchange Commission (SEC).

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) and follow the requirements of the SEC for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted.

The interim condensed balance sheet as of March 31, 2026, the interim condensed statements of operations and comprehensive loss, stockholders' equity and cash flows for the three months ended March 31, 2026 and 2025 are unaudited. These unaudited interim condensed financial statements have been prepared on the same basis as the Company's annual financial statements and reflect all adjustments that are necessary for the fair statement of the Company's financial position, results of operations and cash flows for the interim periods presented. The condensed results of operations for the three months ended March 31, 2026, are not necessarily indicative of the results to be expected for the full year or for any other future annual or interim period. The condensed balance sheet as of December 31, 2025, included herein was derived from the audited financial statements as of that date. These condensed financial statements should be read in conjunction with the Company's audited financial statements and the related notes thereto for the year ended December 31, 2025, included in the Company's Annual Report on Form 10-K, filed with the SEC on March 11, 2026.

Use of Estimates

The preparation of condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the condensed financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying financial statements include, but are not limited to, accrued expenses related to research and development activities and revenue recognition related to collaboration agreements. The Company bases its estimates on historical experience, the current economic

environment, and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Significant Accounting Policies

There have been no material revisions to the Company's significant accounting policies described in Note 2, *Summary of Significant Accounting Policies*, to the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, except for the accounts receivable, revenue recognition and contract liability policies related to the collaboration agreements entered into during the three months ended March 31, 2026, as described below.

Accounts Receivable

The Company's accounts receivable relates to licensing and collaboration arrangements. These accounts receivable are short-term in nature. The Company estimates expected credit losses over the life of the financial assets as of the reporting date based on relevant information about past events, current conditions, and reasonable and supportable forecasts. For the three months ended March 31, 2026 and 2025, the Company had no allowance for credit losses.

Revenue Recognition

Overview

The Company recognizes revenue in accordance with Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers* (ASC 606). Revenue is recognized when promised goods or services are transferred to a customer in an amount that reflects the consideration to which the Company expects to be entitled. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the promises and performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligations. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Collaborative Frameworks and Assessment Under ASC 808 and ASC 606

The Company enters into arrangements that may include elements of collaboration with counterparties, such as joint steering committees or shared development activities. The Company evaluates each arrangement to determine whether the counterparty is acting in the capacity of a customer.

To the extent that the Company transfers goods or services to a counterparty in its capacity as a customer, the Company accounts for such transactions under ASC 606 and presents the related amounts as revenue. Amounts that do not represent transactions with a customer are accounted for under ASC Topic 808, *Collaborative Arrangements* (ASC 808), and presented within the appropriate operating expense line item.

Licensing and Collaboration Arrangements

The Company enters into licensing and collaboration arrangements that may include licenses to intellectual property, as well as research, development, or technical support services necessary to enable the licensee to utilize the underlying technology.

Identification of Performance Obligations

The Company evaluates the nature of its promises in these arrangements to determine whether they are distinct or should be combined. A license of intellectual property is combined with other promised services when the license is not distinct within the context of the contract, such as when the Company's ongoing research or

development activities significantly affect the utility of the licensed intellectual property. When a license and related services are not distinct, they are accounted for as a single combined performance obligation.

Recognition of Revenue

Revenue is recognized either at a point in time or over time, depending on the nature of the underlying performance obligations. Revenue is recognized at a point in time when control of a promised good or service transfers to the customer and the performance obligation is satisfied. Revenue is recognized over time when the Company satisfies a performance obligation over time, including when the Company's performance does not create an asset with an alternative use and the Company has an enforceable right to payment for performance completed to date, or when the customer simultaneously receives and consumes the benefits of the Company's performance.

For performance obligations satisfied over time, the Company measures progress using an appropriate method that faithfully depicts the transfer of control of the underlying services. Depending on the nature of the arrangement, the Company may use an input method, such as costs incurred relative to total estimated costs (cost-to-cost method), when such method best reflects the Company's performance.

For arrangements that provide access to intellectual property or other rights over a defined period without additional performance obligations, revenue is recognized ratably over the contractual term.

Upfront License Fees

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from upfront license fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company determines whether the combined performance obligation is satisfied over time or at a point in time.

Milestone Payments

Contingent milestones at contract inception are estimated at the amount which is not probable of a material reversal and included in the transaction price using the most likely amount method. Milestone payments that are not within the Company's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and therefore the variable consideration is constrained. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each reporting period, the Company re-evaluates the probability of achieving development, regulatory or sales-based milestone payments that may not be subject to a material reversal and, if necessary, adjust the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license and other revenue, as well as earnings, in the period of adjustment..

Sales-Based Royalties and Milestones

For arrangements that include sales-based royalties, including milestone payments based on the volume of sales, the Company will determine whether the license is deemed to be the predominant item to which the royalties or sales-based milestones relate and if such is the case, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Contract Liabilities

Contract liabilities consist primarily of upfront non-refundable payments received under collaboration agreements for which the related performance obligations have not yet been fully satisfied. The Company classifies amounts expected to be recognized as revenue within the next twelve months as contract liabilities, current, with the remainder classified as contract liabilities, noncurrent based on the estimated timing of revenue recognition.

Recently Adopted Accounting Standards

In July 2025, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) No. 2025-05 (ASU 2025-05), *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets* (ASU 2025-05), which provides a practical expedient for entities to estimate expected credit losses on current accounts receivable and current contract assets arising from revenue transactions accounted for under ASC 606. ASU 2025-05 is effective for the Company for annual periods beginning after December 15, 2025, and interim periods within those annual periods. The Company adopted this ASU on a prospective basis during the first quarter of 2026. The adoption did not have a material impact on the Company's financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09), which requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for annual periods beginning after December 15, 2024. The Company adopted this ASU on a prospective basis during the fourth quarter of 2025 and updated its annual disclosures accordingly. The adoption of ASU 2023-09 did not have any effect on the Company's financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2025, the FASB issued ASU No. 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements* (ASU 2025-11), which clarifies the applicability of the interim reporting guidance, the types of interim reporting, and the form and content of interim financial statements in accordance with GAAP. Per the FASB, the amendment does not intend to change the fundamental nature of interim reporting or expand or reduce current interim disclosure requirements but rather provide clarity and improve navigability of the existing interim reporting requirements. ASU 2025-11 is effective for interim periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. ASU 2025-11 may be applied either prospectively or retrospectively for all prior periods presented. The Company is evaluating the impact of this standard on its financial statements and related disclosures.

In December 2025, the FASB issued ASU No. 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities* (ASU 2025-10), which adds guidance to Accounting Standards Codification (ASC) 832 on the recognition, measurement, and presentation of government grants. The guidance establishes a framework for accounting for government grants, including grants related to assets and grants related to income. ASU 2025-10 is effective for the Company for annual periods beginning after December 15, 2028, and interim periods within those annual periods. Early adoption is permitted. The Company is evaluating the impact of this standard on its financial statements and related disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement (Topic 220): Reporting Comprehensive Income - Expense Disaggregation Disclosures, Disaggregation of Income Statement Expenses* (ASU 2024-03), which requires public companies to disclose, in interim and annual reporting periods, additional information about certain expenses in the financial statements. The amendments in this ASU will be effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is evaluating the impact of this standard on its financial statements and related disclosures.

3. Collaboration Revenue

Alnylam Collaboration Agreement

In March 2026, the Company entered into a collaboration agreement with Alnylam Pharmaceuticals, Inc. (Alnylam), pursuant to which both parties agreed to a research collaboration to discover and validate novel gene targets for the potential treatment of cardiovascular disease.

Under the agreement, both parties nominated and aligned on a set of collaboration targets to move forward into the collaboration in late March 2026. Following such alignment, the parties will conduct in vitro and in vivo validation activities under a mutually agreed research plan and budget for a period of twenty-four (24) months (which may be extended for completion of the work). The Company expects to take primary responsibility for the performance of all in vitro and in vivo validation activities throughout the validation term; Alnylam will reimburse the Company for full-time employees and out-of-pocket costs and expenses incurred by the Company in accordance

with the agreed-upon research budget. After completion of the validation activities, Alnylam will be solely responsible, at its own expense, for all development, manufacture, regulatory and commercialization activities for any products directed to a collaboration target. The Company is also entitled to a non-refundable upfront platform access fee of up to $10.0 million. The upfront platform access fee was initially subject to variability based on the number of collaboration targets selected and became fixed at $10.0 million upon finalization of the collaboration target list. Reimbursement of research costs represents variable consideration and is excluded from the transaction price at contract inception as such amounts are fully constrained. These amounts are recognized as revenue as the related costs are incurred.

The Company concluded that the license and research activities represent a single performance obligation that is satisfied over time. Revenue is recognized using a cost-to-cost input method, which measures progress based on costs incurred relative to total estimated costs under the research plan. For the three months ended March 31, 2026, the Company recognized immaterial collaboration revenue related to the upfront platform access fee and reimbursable research costs incurred during the period.

The remaining portion of the upfront payment is recorded as a contract liability and will be recognized as revenue over the remaining validation term as the underlying research services are performed.

The Company may also receive future milestone payments of up to an aggregate of $1.1 billion under the agreement. Development and regulatory milestones will be recognized when the underlying milestone event is achieved and it becomes probable that a significant reversal of cumulative revenue recognized will not occur. Sales-based milestones will be recognized when the related sales occur. As of March 31, 2026, the Company is unable to predict or reasonably estimate the amount or timing of such milestone payments.

As of March 31, 2026, the aggregate amount of the transaction price allocated to the remaining performance obligation under the collaboration agreement was approximately $10.0 million, which the Company expects to recognize over the remaining validation term of approximately 24 months. The transaction price allocated to the remaining performance obligation does not include variable consideration related to reimbursable research costs as they are contingent on actual qualifying costs incurred. Milestone payments were considered variable consideration and were also not included in the transaction price as they are fully constrained. The Company will reassess the transaction price at each reporting period as uncertainties are resolved.

The following table summarizes activity in the Company's total contract liabilities for the three months ended March 31, 2026. Additions to contract liabilities include $0.6 million of upfront payments from an additional immaterial collaboration arrangement.

	Contract Liabilities
Balance as of December 31, 2025	$ —
Addition	10,600
Less: revenue recognized from contract liabilities	(198)
Balance as of March 31, 2026	$ 10,402

4. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consists of the following:

	March 31, 2026	December 31, 2025
	(In thousands)	
Leasehold improvements	$ 26,262	$ 26,244
Manufacturing equipment	19,485	19,485
Laboratory equipment	19,014	19,014
Computer equipment and software	1,893	1,893
Furniture and fixtures	902	902
Construction in progress	100	67
Total property and equipment	$ 67,656	$ 67,605
Less: accumulated depreciation and amortization	(41,696)	(39,933)
Total property and equipment, net	$ 25,960	$ 27,672

Depreciation and amortization expense for the three months ended March 31, 2026 and 2025 was $1.8 million and $2.7 million, respectively.

Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following:

	March 31, 2026	December 31, 2025
	(In thousands)	
Accrued compensation and related expenses	$ 3,188	$ 6,013
Accrued research and development expenses	1,919	1,651
Accrued taxes	406	277
Accrued professional services	62	718
Other current liabilities	455	176
Total accrued and other current liabilities	$ 6,030	$ 8,835

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	March 31, 2026	December 31, 2025
	(In thousands)	
Prepaid expenses	$ 5,023	$ 4,014
Other current assets	25	1,025
Total prepaid expenses and other current assets	$ 5,048	$ 5,039

5. Commitments and Contingencies

Facility Leases

In December 2016, the Company entered into a lease agreement for office and laboratory space in South San Francisco, California. The lease was initially set to expire in May 2025 with two five-year renewal options. In June 2024, the Company amended the lease to extend the term to November 2027. Pursuant to the terms of the amended lease, the Company has one remaining five-year renewal option.

In February 2021, the Company entered into a lease agreement for office and manufacturing space in Union City, California. The lease commenced in May 2021 and has a ten-year term with one five-year renewal option.

Information related to operating lease activity during the three months ended March 31, 2026 was as follows (in thousands):

	Three Months Ended March 31,	
	2026	2025
	(In thousands)	
Operating lease cost	$ 889	$ 889
Variable lease cost	388	368
Short-term lease cost	—	—
Total lease cost	$ 1,277	$ 1,257
Cash paid for amounts included in the measurement of lease liabilities	$ 947	$ 989

As of March 31, 2026, the Company's operating leases had a weighted average remaining lease term of 3.9 years and a weighted average discount rate of 9.1%. As of December 31, 2025, the Company's operating leases had a weighted average remaining lease term of 4.1 years and a weighted average discount rate of 9.1%. Future minimum lease payments under the Company's operating leases as of March 31, 2026 were as follows:

	Amount
	(In thousands)
2026 (nine months remaining)	$ 2,917
2027	3,775
2028	1,471
2029	1,515
2030	1,560
Thereafter	931
Total undiscounted future minimum lease payments	$ 12,169
Imputed interest	(2,052)
Total operating lease liabilities	$ 10,117

Purchase Commitments

The Company enters into contractual agreements with various suppliers in the normal course of its business, including vendors that provide machinery and equipment. All contracts are terminable, with varying provisions regarding termination. In general, if a contract with a specific vendor were to be terminated, the Company would only be obligated for the products or services that the Company had received up to the time of termination.

Contingencies

From time to time, the Company may become involved in litigation and other legal actions. The Company estimates the range of liability related to any pending litigation where the amount and range of loss can be estimated. The Company records its best estimate of a loss when the loss is considered probable. Where a liability is probable and there is a range of estimated loss with no best estimate in the range, the Company records a charge equal to at least the minimum estimated liability for a loss contingency when both of the following conditions are met: (i) information available prior to issuance of the financial statements indicates that it is probable that a liability had been incurred at the date of the financial statements and (ii) the range of loss can be reasonably estimated. The Company was not involved in any material litigation as of March 31, 2026 and December 31, 2025.

Indemnification

In the normal course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amounts of future payments the Company could be required to make under these provisions is not determinable. In addition, the Company has entered into indemnification agreements with its directors and certain officers that may 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. As of March 31, 2026 and December 31, 2025, the Company did not have any material indemnification claims that were probable or reasonably possible and, consequently, has not recorded any related liabilities.

6. Stock-Based Compensation

2024 Inducement Equity Incentive Plan

In September 2024, the Board of Directors (the Board) adopted the Company's 2024 Inducement Equity Incentive Plan (the Inducement Plan), and subject to the adjustment provisions of the Inducement Plan, reserved 1,200,000 shares of the Company's common stock for issuance pursuant to equity awards granted under the Inducement Plan. The Inducement Plan allows the Company to make equity awards to prospective employees of the Company as an inducement to such individual's commencement of employment with the Company. On January 26, 2026, the Board approved an increase of 2,161,000 shares to the number of shares reserved under the Inducement Plan.

Total shares reserved and available for grant under the Inducement Plan as of March 31, 2026, was 2,686,000.

Repricing

On January 22, 2025, the Compensation Committee of the Company's Board approved a repricing of certain outstanding vested and unvested stock option awards under the Amended and Restated 2016 Equity Incentive Plan (the 2016 Plan) and 2021 Plan for eligible employees and certain other service providers (the Repricing Participants). The per share exercise price of eligible stock option awards was reduced to $1.21, the closing price of the Company's common stock on January 24, 2025 (the Repricing Effective Date). To receive the benefit of the repricing, Repricing Participants were required to remain a Service Provider (as such term is defined in the 2016 Plan or 2021 Plan) through the period (the Retention Period) that began on the Repricing Effective Date and ended on July 24, 2025 (the Retention Date) and not exercise any of their repriced stock options prior to the Retention Date. Option holders who exercised their repriced stock options prior to the Retention Date were required to pay the original exercise price per share of such repriced options. No other changes were made to the terms and conditions of the eligible stock option awards. The stock option repricing impacted 4.1 million stock option awards and affected 89 employees and service providers.

On February 6, 2025, the Company's Board approved an option repricing applicable to Faraz Ali, the Company's Chief Executive Officer, with terms mirroring the aforementioned repricing approved on January 22, 2025, except that for Mr. Ali, the options eligible for repricing were limited to options with exercise prices higher than $5.25 per share. The total number of shares underlying Mr. Ali's repriced options was 915,875 shares.

The repricing resulted in a total incremental stock-based compensation expense of $1.3 million, which was calculated using the Black-Scholes option pricing model, of which $1.0 million is associated with vested repriced options as of the Retention Date and were recognized on a straight-line basis over the Retention Period. The remaining $0.3 million of the incremental stock-based compensation expense is associated with unvested repriced options beyond the Retention Period and will be recognized on a straight-line basis over the remaining original vesting periods. For the three months ended March 31, 2026 and 2025, the Company recognized an immaterial amount and $0.4 million, respectively, of incremental stock-based compensation expense,.

2021 Equity Incentive Plan

Under the Company's 2021 Equity Incentive Plan (the 2021 Plan), 4,000,000 shares of the Company's common stock were initially reserved for issuance of equity awards to employees, directors, and consultants, under terms and provisions established by the Board. The number of shares of common stock available for issuance under the 2021 Plan automatically increases on the first day of January for a period of ten years, commencing on January 1, 2022, in an amount equal to the lesser of: 4,000,000 shares; 4% of the outstanding shares of the Company's common stock as of the last day of the immediately preceding year; or such other amount as the board of directors may determine.

The total number of shares reserved and available for grant under the 2021 Plan as of March 31, 2026 was 1,513,435.

Stock Option Activity

The following table summarizes stock option activity:

	Shares	Weighted Average Exercise Price (in dollars)
Outstanding as of December 31, 2025	12,050,796	$ 1.90
Granted	3,482,073	$ 0.91
Exercised	—	$ —
Cancelled	(214,737)	$ 0.90
Outstanding as of March 31, 2026	15,318,132	$ 1.72

Stock option awards granted to employees generally vest over a four-year period. The contractual term of stock option awards is generally 10 years from the grant date.

Stock Option Valuation

The fair value of the Company's stock option awards is estimated on the date of grant using the Black-Scholes option pricing model using the following assumptions:

	Three Months Ended March 31,	
	2026	2025
Expected term (in years)	6.0	6.0
Expected volatility	85%	91%
Risk-free interest rate	3.9%	4.3% – 4.5%
Expected dividend yield	—%	—%

Restricted Stock Units

Restricted stock units (RSUs) are awards that entitle the holder to receive freely tradable shares of the Company's common stock upon the completion of a specific period of continued service. RSUs generally vest over a two to four year period and are subject to forfeiture if employment terminates prior to the release of vesting restrictions. RSUs are valued at the market price of the underlying common stock on the date of grant. The Company recognizes noncash compensation expense for the fair value of RSUs on a straight-line basis over the requisite service period of the awards. The following table summarizes activity of RSUs granted to employees with service-based vesting under the 2021 Plan.

	Shares	Weighted Average Grant Date Fair Value per Share (in dollars)
Unvested as of December 31, 2025	1,536,234	$ 2.39
Granted	1,237,092	$ 0.91
Vested	(238,593)	$ 3.01
Forfeited	(16,796)	$ 2.22
Unvested as of March 31, 2026	2,517,937	$ 1.61

2021 Employee Stock Purchase Plan

Under the Company's 2021 Employee Stock Purchase Plan (the ESPP), the Company initially reserved 800,000 shares for future issuance. The number of shares of common stock available for issuance under the ESPP automatically increases on the first day of each fiscal year for a period of ten years beginning with 2022 in an amount equal to the lesser of: 800,000 shares; 1% of the outstanding shares of the Company's common stock as of the last day of the immediately preceding year; or such other amount as the Board may determine. As of March 31, 2026, 3,074,594 shares were reserved for future issuance under the ESPP. Under the Company's ESPP, employees

are generally eligible to participate and can purchase shares on each purchase date established semi-annually through payroll deductions at the lower of 85% of the fair market value of the Company's stock at the commencement of the offering period or each purchase date of the offering period. Each offering period spans six months. The ESPP permits eligible employees to purchase common stock through payroll deductions for up to 15% of qualified compensation, up to an annual limit of $25,000 per the Internal Revenue Service. For the three months ended March 31, 2026 and 2025, the stock-based compensation expense for ESPP was not material.

Stock-Based Compensation

The following table summarizes stock-based compensation recognized in the Company's condensed statements of operations and comprehensive loss:

	Three Months Ended March 31,	
	2026	2025
Research and development	$ 1,201	$ 2,047
General and administrative	995	1,684
Total stock-based compensation	$ 2,196	$ 3,731

7. Term Loan

Loan Agreement

On August 6, 2024, the Company entered into the Loan Agreement with Silicon Valley Bank (SVB). As of December 31, 2025, all of the term loan commitments expired under the Loan Agreement and no term loans were outstanding. The Loan Agreement provides that an additional loan of $20.0 million may be available at SVB's discretion, subject to specified conditions.

8. Stockholders' Equity

Lender Warrant

In connection with the Loan Agreement, the Company issued to SVB a warrant to purchase up to 171,848 shares of common stock (the Lender Warrant). The Lender Warrant became exercisable for 73,649 shares upon closing (the Initial Lender Warrant) at an exercise price of $2.55 per share. The Initial Lender Warrant was classified as equity and its fair value was recorded in the stockholders' equity section of the balance sheet. The Lender Warrant expires on August 6, 2034.

The Lender Warrant was eligible to become exercisable for up to an additional 98,199 shares pro-rated based on amounts actually advanced for the various tranches under the Loan Agreement (the Remaining Lender Warrant). Following the expiration of the tranches under the Loan Agreement described in Note 7, *Term Loan*, the Remaining Lender Warrant expired as of December 31, 2025.

"At-the-Market" Equity Offering

On August 10, 2022, the Company entered into a sales agreement (the Sales Agreement) with Leerink Partners LLC to establish an "at-the-market" (ATM) offering defined in Rule 415 under the Securities Act. Pursuant to the Sales Agreement, the Company is permitted to offer and sell, from time to time, shares of its common stock having a maximum aggregate offering price of up to $75.0 million. In January 2025, the Company sold 822,566 shares of common stock under the ATM offering for net proceeds of $0.9 million, after deducting commissions and offering costs of $0.3 million. As of March 31, 2026, the Company may issue and sell up to approximately $69.8 million of common stock under the ATM offering.

Follow-On Offering

On December 15, 2025, the Company completed an underwritten public offering of 50,000,000 units, priced at a public offering price of $1.20 per unit, with each unit consisting of one share of its common stock and a warrant to purchase one share of its common stock at an exercise price of $1.50 per share, which will be immediately exercisable and will expire five years from the date of issuance (December 2025 Warrants), under its registration

statement on Form S-3 (File No. 333-286005). The Company received net proceeds of $55.8 million, after deducting underwriting discounts and commissions of $3.6 million and other offering expenses of $0.6 million.

On March 5, 2025, the Company completed an underwritten public offering of 75,000,000 units, priced at a public offering price of $0.70 per unit, with each unit consisting of one share of its common stock, a warrant to purchase one share of its common stock at an exercise price of $0.80 per share, which will be immediately exercisable and will expire five years from the date of issuance (a Series A Warrant) and a warrant to purchase one-half of a share of its common stock at an exercise price of $0.70 per share, which will be immediately exercisable and expire on June 30, 2026 (a Series B Warrant), under its registration statement on Form S-3 (File No. 333-266741). The Company received net proceeds of approximately $48.8 million, after deducting underwriting discounts and commissions of approximately $3.2 million and other offering expenses of approximately $0.5 million.

The Company analyzed the December 2025, Series A, and Series B Warrants under ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815-40, *Derivatives and Hedging - Contracts in Entity's Own Equity*, and concluded that they were not liabilities, were indexed to its own stock and met all other conditions for equity classification. Accordingly, the Company has classified them as permanent equity.

As of March 31, 2026, total shares of common stock reserved for issuance, on an as-if converted basis, are as follows:

	March 31, 2026
Outstanding stock options and restricted stock units	17,836,069
Outstanding Lender Warrant	73,649
Outstanding Series A and Series B Warrants	109,231,250
Outstanding December 2025 Warrants	50,000,000
Shares available for further issuance under the 2024 Inducement Equity Incentive Plan	2,686,000
Shares available for further issuance under the 2021 Equity Incentive Plan	1,513,435
Shares available for further issuance under the 2021 Employee Stock Purchase Plan	3,074,594
Total	184,414,997

9. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

Level 1 - Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2 - Inputs other than quoted market prices included in Level 1 are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument’s anticipated life.

Level 3 - Inputs reflect management’s best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

The following tables summarize the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy:

	Valuation Hierarchy	March 31, 2026 Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
		(In thousands)			
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 77,054	$ —	$ —	$ 77,054
Total financial assets		$ 77,054	$ —	$ —	$ 77,054

	Valuation Hierarchy	December 31, 2025 Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
		(In thousands)			
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 98,424	$ —	$ —	$ 98,424
Total financial assets		$ 98,424	$ —	$ —	$ 98,424

Money market funds are classified as Level 1 because they are valued using quoted market prices in active markets for identical assets.

The carrying amount of the Company's remaining financial assets and liabilities, which include cash, receivables and payables, approximate their fair values due to their short-term nature.

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains a significant majority of its cash balances with a single financial institution, with the remainder held at other financial institutions. The Company's cash balances exceed federally insured limits. The Company has not experienced any losses on its cash balances and management monitors the creditworthiness of these institutions and believes the Company is not exposed to significant credit risk related to these balances.

10. Income Taxes

For the three months ended March 31, 2026 and 2025, the Company did not record any income tax expense or benefit. The Company has recorded a full valuation allowance against its U.S. federal and state deferred tax assets as the Company believes it is more likely than not that the benefit will not be realized.

11. Net Loss Per Share

Basic and diluted loss per share are computed by dividing net loss by the weighted-average number of common shares outstanding during the reporting period. The following potentially dilutive securities were not included in the calculation of diluted net loss per share as of the periods presented because the effect would have been anti-dilutive:

	March 31, 2026	March 31, 2025
Outstanding stock options and restricted stock units	17,836,069	13,417,046
Outstanding Lender Warrant	73,649	171,848
Outstanding Series A and Series B Warrants	109,231,250	112,500,000
Outstanding December 2025 Warrants	50,000,000	—
Total	177,140,968	126,088,894

12. Workforce Reduction

During the three months ended March 31, 2026, the Company recognized $0.2 million of additional charges related to its workforce reduction implemented in March 2025, primarily related to employee cash severance and

continuing health benefits. The Company expects to incur substantially all of the remaining charges of $0.5 million by the end of the second quarter of 2026.

13. Segment Reporting

The Company is a clinical-stage biotechnology company focused on discovering, developing and delivering curative therapies that address the underlying drivers of heart disease and has one operating and reportable segment. The Company's chief operating decision maker (CODM) is the chief executive officer.

The statement of operations includes research and development expenses, general and administrative costs, interest income, and income taxes; the Company has not generated any product revenue. In addition to reviewing the expenses in the Company's statement of operations, the CODM is regularly provided with operating expenses by function. The CODM does not review assets at a different asset level or category than the amounts disclosed in the Company's balance sheet. The Company's long-lived assets are located in the United States.

The following table provides information about the Company's operating expenses by function and includes a reconciliation to net loss.

	Three Months Ended March 31,	
	2026	2025
Revenue		
Collaboration revenue	$ 225	$ —
Operating expenses:		
Research and development		
Clinical	5,376	5,947
Manufacturing (pre-commercial)	3,465	5,447
Research	2,958	5,919
Other	3,044	3,763
Total research and development	14,843	21,076
General and administrative	5,447	6,462
Total operating expenses	20,290	27,538
Loss from operations	(20,065)	(27,538)
Other income, net:		
Interest income	793	635
Other income, net	—	39
Total other income, net	793	674
Net loss before income tax expense	(19,272)	(26,864)
Income tax expense	—	—
Net loss	$ (19,272)	$ (26,864)

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and related notes thereto for the year ended December 31, 2025, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 11, 2026.

In addition to historical financial information, this discussion and analysis and other parts of this report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended, based upon current expectations that involve risks, uncertainties and assumptions. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A. below. You should carefully read the "Risk Factors" to gain an understanding of the 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."

Overview

We are a clinical-stage biotechnology company focused on discovering, developing and delivering potentially curative therapies that address the underlying drivers of heart disease. Heart disease remains a leading cause of death in the world. We believe the emerging insights into the genetic causes of cardiovascular conditions and increased recognition for precision medicine approaches has created an opportunity to change the treatment paradigm for heart disease, and in doing so improve and extend the lives of patients.

Early on in our company history, we invested in differentiated capabilities to enable modality-agnostic target identification and validation, anchored in human genetics and the use of human disease models. To support our initial focus on gene therapy candidates, we also internalized expertise in capsid engineering, novel promoter constructs and manufacturing anchored on the use of adeno-associated viruses (AAVs) as the method of delivery to the heart. That proprietary expertise has directly informed the discovery, design, optimization and production of our pipeline.

We are primarily focused on advancing our clinical-stage gene therapy candidates, TN-201 for *MYBPC3*-associated hypertrophic cardiomyopathy (HCM), and TN-401 for *PKP2*-associated arrhythmogenic right ventricular cardiomyopathy (ARVC). Each candidate is currently in Phase 1b/2 trials to establish the safety profile of two different doses in adults with disease due to pathogenic/likely pathogenic mutations. We anticipate that data generated to date and over the course of 2026 will support our pursuit of regulatory alignment on late-stage development for these gene therapy product candidates. A third internally discovered clinical-stage candidate, TN-301, is a highly specific small molecule inhibitor of histone deacetylase 6 (HDAC6) with potentially broad utility in heart failure with preserved ejection fraction (HFpEF) and other cardiac, metabolic, muscular and pulmonary diseases, including but not limited to Duchenne muscular dystrophy (DMD), genetic dilated cardiomyopathy (DCM) and pulmonary arterial hypertension (PAH).

For programs arising out of our modality agnostic drug discovery platform that address relatively rare conditions our strategy is to develop, manufacture and commercialize at least some of these programs on our own, although we may selectively consider partnerships to access technology, accelerate our progress, or improve our global reach to patients. For example, in March 2026, we entered into a multi-target research collaboration with Alnylam Pharmaceuticals, Inc. (Alnylam), to identify and validate novel gene targets for the potential treatment of cardiovascular disease. Importantly, this agreement takes advantage of our modality agnostic discovery know-how and provides reimbursement for research efforts. Where our discovery efforts lead to product candidates intended for relatively prevalent indications, our strategy is to out-license or partner such programs.

TN-201 is our investigational gene therapy for individuals with HCM due to *MYBPC3* gene mutations. These mutations result in a deficiency of myosin-binding protein C (MyBP-C), which in turn can cause the heart walls of affected individuals to become significantly thickened, leading to fibrosis, abnormal heart rhythms, cardiac dysfunction, heart failure and death. HCM is a chronic, progressive condition, and those diagnosed with the disease often experience significant impairment in overall quality of life and may be at higher risk for serious complications and co-morbidities. TN-201 utilizes a recombinant AAV9 capsid and is designed to deliver a

working *MYBPC3* gene to specific cells of the heart in order to produce MyBP-C and thereby potentially slow or even reverse the course of *MYBPC3*-associated HCM following a single infusion.

MyPEAK™-1 is our Phase 1b/2 multi-center, open-label clinical trial, designed to assess the safety, tolerability and efficacy of a one-time intravenous infusion of TN-201. Enrollment and dosing in both the 3E13 vg/kg dose (Cohort 1) and 6E13 vg/kg dose (Cohort 2) cohorts are complete. A per protocol review by the independent data safety monitoring board (DSMB) of all available data from the first six patients dosed determined that TN-201 had an acceptable safety profile to proceed with dosing expansion cohorts at either dose level. We are enrolling additional patients in MyPEAK-1 to further characterize dose response and inform dose selection for late-stage clinical trials.

In November 2025, we presented interim data from MyPEAK-1 at the American Heart Association's Scientific Sessions 2025, with simultaneous publication in *Cardiovascular Research*. Interim data presented included safety, biopsy and efficacy results for the three patients enrolled in Cohort 1 with follow-up ranging from Week 52-78, and safety and available assessments for the patients in Cohort 2 who had post-dose assessments ranging from Week 12-26 as of the July 2025 data cut-off. Patient 5 was lost to further follow-up after week 12. TN-201 was generally well tolerated across both dose cohorts and no dose-limiting toxicities were observed. Reversible, asymptomatic liver enzyme elevations (Grade 1-3) were the most common treatment-related adverse events (AEs) reported. There were two treatment-related AEs classified as serious either due to inpatient administration of steroids or extended monitoring; a Grade 2 transaminase elevation that responded to steroids and a Grade 1 elevation of complement factors that resolved without additional intervention. Adjustments to monitoring and immunosuppression during Cohort 1 resulted in faster tapers and lower cumulative corticosteroid doses in Cohort 2, despite the higher TN-201 dose.

DNA and RNA analyses of cardiac biopsy samples from all three patients in Cohort 1 showed evidence of sustained presence of TN-201 DNA in the heart and increasing mRNA expression over time. The first patient in Cohort 2 with serial biopsy data (Patient 6) had a greater than 2-fold increase in cardiac transduction and RNA expression at Week 12 relative to the average for these measures observed across Cohort 1 patients. MyBP-C protein levels across Cohort 1 increased over time by an average of 4% from the first biopsy taken to Week 52. The first evaluable patient in Cohort 2 (Patient 6) demonstrated a clear dose response, and early MyBP-C expression increased by 14% after only 12 weeks post-dose.

All patients with greater than 26 weeks of follow-up demonstrated improvement in at least one parameter of disease, across biomarkers, hypertrophy and heart failure symptoms. Cardiac troponin I, a predictive risk factor of adverse cardiac outcomes such as ventricular arrhythmias, sudden cardiac death, and progression to end-stage heart failure, declined by as much as 74% from baseline, to normal or near-normal levels in all Cohort 1 patients. NT-proBNP, a biomarker of cardiac muscle strain, improved or remained stable in two of three Cohort 1 patients. All three patients in Cohort 1 showed evidence of significant improvement in one or more measures of hypertrophy at Week 52, with notable reductions in left ventricular posterior wall thickness (LVPWT) of between 21% and 39%. Greater LVPWT is an independent risk factor for reduced long-term survival after septal myectomy. Two out of three Cohort 1 patients saw reductions from baseline in left ventricular mass index (LVMI) of between 12% and 22% at Week 52. In the first Cohort 2 patient for whom Week 26 data were available (Patient 4), cardiac troponin I remained within the normal range and NT-proBNP remained stable. LVPWT and LVMI also remained stable at Week 26. New York Heart Association (NYHA) classification, a measure of the impact of heart failure symptoms on activities of daily living, improved in all patients by at least one class by Week 26, and all Cohort 1 patients were NYHA Class I (asymptomatic) as of the data cutoff date. Longer-term follow-up for all patients is required to further inform our understanding of TN-201's potential as a treatment for *MYBPC3*-associated HCM.

We expect to present longer-term Cohort 1 and interim Cohort 2 data in the second quarter of 2026. In the second half of 2026, one-year Cohort 2 data and two-year Cohort 1 data from MyPEAK-1 are anticipated. We are also pursuing alignment with regulatory authorities on pivotal trial plans for TN-201 and plan to provide an update on progress by year end.

Despite advances in the treatment of the obstructive HCM in recent years with the approval of cardiac myosin inhibitors, there are no approved treatments for those with the non-obstructive form of disease or those diagnosed before the age of 18. Recognizing the urgent medical need among pediatric patients, we initiated MyClimb, a retrospective and prospective natural history study of pediatric patients to characterize the outcomes, burden of illness, risk factors, quality of life, and biomarkers associated with disease progression in pediatric patients. MyClimb complements existing disease registries focused primarily on adult patient HCM populations and may

support and expedite the development of TN-201 in the pediatric patient population. MyClimb completed enrollment of more than 200 individuals and is believed to be the largest study of pediatric individuals with *MYBPC3*-associated HCM ever conducted. Initial data indicated that 93% of participants had the nonobstructive HCM phenotype, for which there are currently no approved treatment options and that genotype was a significant predictor of risk. The data also revealed that LVMI may serve as a surrogate marker for poor long-term outcomes and as an appropriate marker to evaluate the early effectiveness of TN-201's potential in a future pivotal trial.

The FDA has granted TN-201 Fast Track, Orphan Drug and Rare Pediatric Drug Designations. TN-201 has also received orphan medicinal product designation from the European Commission (EC).

TN-401 is our AAV9-based gene therapy for the treatment of ARVC due to disease-causing variants in the *PKP2* gene. ARVC, also known as arrhythmogenic cardiomyopathy or ACM, is a chronic, progressive disease characterized by frequent, severe, and potentially life-threatening ventricular arrhythmias. The disease is associated with adverse heart remodeling, fibrosis, cardiac dysfunction, significant impairment to patients' overall quality of life, as well as an elevated risk of sudden cardiac death. *PKP2* mutations are the most common genetic cause of ARVC and result in insufficient expression of a protein needed for proper functioning of the desmosomal complex that maintains physical connections and electrical signaling between heart muscle cells. TN-401 utilizes a recombinant AAV9 capsid and is designed to deliver a working *PKP2* gene to specific cells of the heart in order to produce plakophilin protein and thereby potentially slow or even reverse the course of *PKP2*-associated ARVC following a single infusion.

RIDGE™-1 is our Phase 1b/2 multi-center, open-label clinical trial, designed to assess the safety, tolerability and efficacy of a one-time intravenous infusion of TN-401. Enrollment and dosing in both the 3E13 vg/kg dose (Cohort 1) and 6E13 vg/kg dose (Cohort 2) cohorts are complete. In January 2026, the DSMB for RIDGE-1 reviewed all available data from Cohort 1 and Cohort 2, determined that TN-401 had an acceptable safety profile and endorsed proceeding into expansion cohorts at either dose level, per protocol. We are enrolling additional patients in RIDGE-1 to inform dose selection for late-stage clinical trials.

In December 2025, we presented interim data from RIDGE-1, including safety, biopsy and arrhythmia results as of the October 2025 data cut-off for three patients enrolled in Cohort 1, with follow-up ranging from Week 20 to Week 40. TN-401 was generally well tolerated and no dose-limiting toxicities were observed. AEs were generally mild, asymptomatic and manageable and a majority of the AEs were deemed unrelated to TN-401. Among the AEs related to TN-401, there was a Grade 1 incidence of elevated troponin levels categorized as a serious AE due to inpatient monitoring. There were no incidents of thrombotic microangiopathy or cardiotoxicities observed and no arrhythmias associated with TN-401 occurred. Additionally, no Cohort 1 patients had experienced an implantable cardioverter defibrillator (ICD) shock post-treatment and all had tapered off prophylactic immunosuppressive medicines.

Serial biopsies taken at baseline and Week 8 post dose for Patients 1 and 2 provided consistent evidence of TN-401 transduction and expression. At Week 8, TN-401 robust mRNA expression was observed across all three patients. Post-treatment protein levels of PKP2 increased significantly in Patients 1 and 2 by a mean of 10% from baseline to Week 8 as measured by liquid chromatography–mass spectrometry normalized to myosin heavy chain, a motor protein in the sarcomere found exclusively in cardiomyocytes. Change in PKP2 protein levels for Patient 3 appeared slightly lower than baseline despite having the highest levels of TN-401 mRNA expression across Cohort 1. This confounding result for PKP2 protein level falls within the standard deviation of these methods and may be due to the inherent variability in sampling biopsies. A second post-dose biopsy will be collected and analyzed from Week 52 per protocol for all patients.

All three patients in Cohort 1 had severe electrical instability with a history of ventricular arrhythmias and had undergone a catheter ablation procedure, an elective procedure to reduce ventricular tachycardia recurrence. At baseline, each Cohort 1 patient met the enrollment criteria of greater than 500 premature ventricular contractions per 24 hours as measured over a seven-day monitoring period prior to dosing. Two of three patients experienced significant and clinically meaningful improvements in electrical instability, as measured by seven-day ambulatory monitoring of premature ventricular contractions (PVCs) following dosing. Patient 1 experienced a decrease in PVCs by 46% as of their most recent (Week 40) visit, while Patient 2 experienced a decrease in PVCs of 89% as of their most recent (Week 32) visit. Non-sustained ventricular tachycardia (NSVT) burden was eliminated or stable six months after treatment with TN-401. Patient 1 had a low NSVT count at baseline, which remained low at their most recent visit (Week 40). Patient 2 also had a substantial NSVT burden of 78 counts per 24-hour period at baseline that dropped to zero and remained stable by Week 32. Meaningful changes in PVCs or NSVTs were not

expected nor observed for Patient 3 as of the data cut off, which was less than six months following treatment with TN-401. Other potential measures of clinical response including QRS duration, T wave inversions, heart function and NYHA class were in the normal range or remained stable for all three Cohort 1 patients during the post-dose follow-up period. We expect to present one-year Cohort 1 data and initial Cohort 2 data in the first half of 2026, with interim Cohort 2 results anticipated in the second half of the year. We are also pursuing alignment with regulatory authorities on pivotal trial plans for TN-401 and plan to provide an update on progress by year end.

In February 2025, we were awarded a Clinical Grant (Clin2) of $8.0 million from CIRM, a state of California Agency that funds regenerative medicine, stem cell, and gene therapy research. Proceeds from the grant will help fund clinical trial costs for our ongoing Phase 1b/2 RIDGE-1 clinical trial of TN-401 gene therapy. RIDGE-1 is being conducted at multiple clinical trial sites with ARVC expertise at leading cardiology centers in the U.S. and United Kingdom.

To support our development efforts for TN-401, we have initiated RIDGE, a global noninterventional study to collect treatment history and seroprevalence to AAV9 antibodies data among ARVC patients who carry pathogenic or likely pathogenic *PKP2* gene mutations. Interim data from RIDGE, believed to be the largest natural history study of adults with *PKP2*-associated ARVC, was presented at Heart Rhythm Society's annual meeting in April 2025. Adults with *PKP2*-associated ARVC experience a high burden of arrhythmias despite treatments with anti-arrhythmic medications, beta blockers and the anti-arrhythmic flecainide, as well as surgical interventions such as ablation and ICD placement. Further, current treatments appeared to do little to halt or prevent progressive structural changes to the heart that occur as a result of *PKP2* mutations. A large majority of adults with *PKP2*-associated ARVC would be eligible to participate in RIDGE-1 based on low levels of pre-existing antibodies to AAV9.

TN-401 has received Orphan Drug and Fast Track designation from the FDA and orphan medicinal product designation from the EC.

We are also advancing TN-301, a highly specific HDAC6 inhibitor that has potential utility in HFpEF and other cardiac, metabolic, muscular and pulmonary diseases. TN-301 was initially discovered and validated as having cardioprotective qualities in preclinical studies of a rapidly worsening mouse model of *BAG3* mutant DCM. HDAC6 is a cytoplasmic enzyme known to regulate diverse cellular processes. Based on TN-301's multi-modal mechanism of action, that includes reductions in inflammation, oxidative stress, fibrosis, and metabolic dysregulation, as well as improvements in autophagy, protein quality control, mitochondrial metabolism, and lipid metabolism, TN-301 may be well suited to the treatment of HFpEF, as well as other cardiac, metabolic, muscular and pulmonary disorders where there is strong alignment between TN-301's mechanism and the pathophysiology of disease.

We shared positive data from our Phase 1 clinical trial of TN-301 in healthy participants at the 2023 Heart Failure Society of America Annual Scientific Meeting. TN-301 was generally well tolerated across the broad range of doses studied. Pharmacokinetic results showed overall dose proportionality with a half-life supportive of once-daily dosing. Increasing doses and exposures with TN-301 correlated with increased pharmacodynamic effects. There were no changes in histone acetylation with TN-301 underscoring the selectivity of TN-301 for HDAC6 and potentially reducing the risk of off target effects. Extensive *in vitro* and *in vivo* studies have also shown that TN-301 addresses diverse pathological processes with direct and systemic benefits in models of HFpEF. In comparative studies, selective HDAC6 inhibition as a single agent has been shown to have similar efficacy to empagliflozin, an SGLT2 inhibitor which is approved for the treatment of HFpEF and co-administration of our HDAC6 inhibition with a SGLT2 inhibitor in a HFpEF mouse model demonstrated additive benefit. Taken together, these data support continued development of TN-301 as a potential treatment for patients with HFpEF and other severe diseases including those outside of cardiology in which inflammation, fibrosis and metabolic dysregulation may be implicated.

Based on our observations of TN-301's mechanism and evidence of efficacy for an approved pan-HDAC agent, we are also exploring the development of TN-301 for DMD, a condition caused by genetic mutations in the *dystrophin* gene, leading to absence of functional dystrophin protein in the heart and skeletal muscle. The muscle pathologies that underlie muscle wasting in the absence of dystrophin include inflammation, fibrosis, altered regeneration, mitochondrial dysfunction and disrupted autophagic flux – all processes that can be improved by HDAC6 inhibition.

At the Muscular Dystrophy Association Clinical & Scientific Congress 2026, we presented results from preclinical studies comparing TN-301 with the FDA-approved pan HDAC inhibitor, givinostat, in a well-established mouse model of DMD, and in human induced Pluripotent Stem Cell (iPSC)-derived cardiomyocytes from DMD

patients. After five weeks of once-daily oral dosing, TN-301 showed a statistically significant increase in forelimb grip strength in *mdx* mice at both 3 mg/kg and 30 mg/kg compared to vehicle with both doses of TN-301 achieving wildtype levels of grip strength after five weeks. Further, TN-301 demonstrated greater efficacy at both doses compared to the 10 mg/kg dose of givinostat, which corresponds to the clinically relevant dose used in DMD patients. Notably, the effects of TN-301 at both doses approached those observed with the 30 mg/kg dose of givinostat, a level that is not tolerated in humans.

In engineered heart tissues derived from human DMD-induced iPSCs, TN-301 corrected calcium handling abnormalities, a key driver of DMD cardiomyopathy, including beat-to-beat fluctuations in calcium amplitude. In contrast, givinostat exacerbated calcium handling irregularities. In an experiment of DMD patient-derived iPSC cardiomyocytes designed to measure oxygen consumption and mitochondrial stress, both known contributors to DMD cardiomyopathy, TN-301 corrected basal and maximal respiration whereas givinostat worsened both measures. Taken together, these data support advancement of TN-301 as a potential DMD therapy with benefits for both skeletal and cardiac muscle and reduced liabilities compared to pan-HDAC inhibitors.

We plan to advance TN-301 toward clinical trials in patients in order to generate proof-of-activity data, with HFpEF and DMD being among the most promising potential indications identified to date. Consistent with our strategy, we believe that TN-301's late-stage development and commercialization in large indications would best be led by a strategic pharmaceutical partner with global resources to explore the full potential of the molecule.

The FDA has granted both Orphan Drug and Rare Pediatric Drug Designations to TN-301 as a treatment for DMD.

In addition to our clinical-stage candidates, we have multiple early-stage programs using various therapeutic approaches, including gene addition, gene editing, gene silencing, and cellular regeneration to address other forms of rare and/or prevalent forms of heart disease. We do not have any products approve for sale and have not generated any product revenue to date.

Results of Operations

Comparison of the Three Months Ended March 31, 2026 and 2025:

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

(in thousands, except percentages)	Three Months Ended March 31, 2026	2025	$ Change	% Change
Revenue				
Collaboration revenue	$ 225	$ —	$ 225	NM
Operating expenses:				
Research and development	14,843	21,076	(6,233)	(30%)
General and administrative	5,447	6,462	(1,015)	(16%)
Total operating expenses	20,290	27,538	(7,248)	(26%)
Loss from operations	(20,065)	(27,538)	7,473	(27%)
Other income, net:				
Interest income	793	635	158	25%
Other income, net	—	39	(39)	(100%)
Total other income, net	793	674	119	18%
Net loss	$ (19,272)	$ (26,864)	$ 7,592	(28%)

NM - Not Meaningful

Collaboration Revenue

Collaboration revenue for the three months ended March 31, 2026 was $0.2 million, compared to none in the prior year period. The increase was primarily driven by the amortization of upfront fees associated with collaboration arrangements entered into during the first quarter of 2026.

Research and Development Expenses

Research and development activities account for a significant portion of our operating expenses. Research and development expenses relate primarily to discovery and development of our research programs, product candidates and proprietary platform technology, and are recognized as incurred. Internal research and development costs include, among others, employee-related costs (including salaries, benefits and stock-based compensation for employees engaged in research and development functions), laboratory supplies, other non-capital equipment utilized for in-house research, and allocated overhead costs. External research and development expenses include, among others, fees paid to contract research organizations to execute preclinical studies and clinical trials on our behalf, and consulting fees. We do not allocate our costs by research program, product candidate or proprietary platform technology, as a significant amount of research and development expenses represent internal costs, which are deployed across our programs, product candidates, proprietary platform technology, and other activities.

We expense all research and development costs in the periods in which they are incurred. Costs of certain research and development activities are recognized based on estimates derived from a number of factors, including an evaluation of the progress of the activities, as well as input from external service providers.

The process of conducting the necessary research to advance through the clinical stages and ultimately obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we cannot reasonably estimate or know the nature, timing or estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates. The level of our research and development expenses over the next twelve months will be subject to operational decisions made following data generated from our MyPEAK-1 and RIDGE-1 clinical trials and our ability to achieve regulatory alignment on our pivotal trial plans for our TN-201 and TN-401 programs.

The following table summarizes our research and development expenses for the periods presented:

(in thousands, except percentages)	Three Months Ended March 31, 2026	2025	$ Change	% Change
Clinical	$ 5,376	$ 5,947	$ (571)	(10%)
Research	2,958	5,919	(2,961)	(50%)
Manufacturing (pre-commercial)	3,465	5,447	(1,982)	(36%)
Other	3,044	3,763	(719)	(19%)
Total research and development expenses	$ 14,843	$ 21,076	$ (6,233)	(30%)

Research and development expenses were $14.8 million and $21.1 million for the three months ended March 31, 2026 and 2025, respectively. The year-over-year decrease of $6.2 million, or 30%, was primarily due to:

- a $3.0 million decrease in research expenses, reflecting lower employee-related costs driven by the workforce reduction implemented in March 2025 (the 2025 Workforce Reduction) and reduced lab supply and service costs; and
- a decrease of $2.0 million in manufacturing costs reflecting lower employee-related costs driven by the 2025 Workforce Reduction and lower facility maintenance fees and depreciation expense.

General and Administrative

General and administrative expenses consist of personnel-related costs (including salaries, benefits and stock-based compensation for our employees in finance, human resources and other administrative functions), legal fees, professional fees incurred for accounting, audit and tax services, information technology and facility costs not otherwise included in research and development expenses. Legal fees primarily include those related to corporate and intellectual property-related matters.

We will continue to incur legal, accounting, insurance and other expenses in operating our business as a public company, including costs associated with regulatory and compliance activities. As with our research and development, the level of our general and administrative expenses over the next twelve months will be subject to operational decisions made following data generated from our MyPEAK-1 and RIDGE-1 clinical trials and our ability to achieve regulatory alignment on our pivotal trial plans for our TN-201 and TN-401 programs.

General and administrative expenses were $5.4 million and $6.5 million for the three months ended March 31, 2026 and 2025, respectively. The year-over-year decrease of $1.0 million, or 16%, was primarily due to decreases in employee-related costs driven by the 2025 Workforce Reduction and lower professional fees.

Interest Income

Interest income primarily consists of interest earned on our cash and cash equivalents balances. In prior period, interest income also included amounts earned on marketable securities. Interest income was $0.8 million and $0.6 million for the three months ended March 31, 2026 and 2025, respectively. The year-over-year increase of $0.2 million was primarily due to average higher cash and cash equivalents balances.

Net Loss

Net loss for the three months ended March 31, 2026, was $19.3 million, compared to a net loss of $26.9 million for the three months ended March 31, 2025.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have generated limited collaboration revenue and no product revenue, and we have incurred significant net losses and negative cash flows from operations. From our inception through March 31, 2026, we have funded our operations primarily from the sale and issuance of our equity securities. As of March 31, 2026, we had cash and cash equivalents of $80.9 million and an accumulated deficit of $624.3 million.

CIRM Grant

In February 2025, we announced we were awarded an $8.0 million grant from the CIRM to support RIDGE-1. The award is payable to us upon achievement of certain clinical milestones. We expect this grant to provide funding for a portion of our research and development activities, subject to the achievement of applicable milestones and compliance with the grant terms.

Loan Agreement

On August 6, 2024, we entered into a Loan Agreement with Silicon Valley Bank (SVB). As of December 31, 2025, all of the term loan commitments expired under the Loan Agreement and no term loans were outstanding. The Loan Agreement provides that an additional loan of $20.0 million may be available at SVB’s discretion, subject to specified conditions.

Funding Requirements

We expect that we will continue to incur operating losses over the foreseeable future. Our operating expenses may increase in the future, if and as we:

- continue to advance our lead product candidates, TN-201, TN-401 and TN-301;
- expand the scope of our existing clinical trials and transition into late-stage clinical development;
- seek regulatory and marketing approvals of any of our product candidates that successfully complete clinical trials;
- establish commercial-scale manufacturing capabilities;
- expand our operational, financial, and information systems and personnel to support our future product development and commercialization efforts;

- seek to identify additional research programs and additional product candidates;
- initiate preclinical studies and clinical trials for any additional product candidates we identify;
- advance our future product candidates into clinical development;
- maintain, develop, expand, enforce, defend and protect our intellectual property portfolio; and
- continue to operate as a public company.

Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to meet our working capital and capital expenditure needs through at least the next twelve months following the date of this Quarterly Report on Form 10-Q.

In order to complete the development of our product candidates and commercialize our product candidates, if approved, we will require substantial additional funding. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our operations through public or private equity offerings, debt financings or other capital sources, which may include strategic collaborations or other arrangements with third parties, or other sources of financing. We may not be able to raise additional capital on terms acceptable to us 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 or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments or engage in merger, consolidation, licensing or asset sale transactions. If we raise funds through strategic collaborations, partnerships and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. If we are unable to raise additional capital on acceptable terms when needed, our business, results of operations, and financial condition would be adversely affected.

Our ability to raise additional funds may be adversely impacted by global economic conditions or disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, future commercialization efforts or other operations. Because of the numerous risks and uncertainties associated with research, product development and commercialization of product candidates, we are unable to predict the timing or amount of our working capital requirements or when or if we will be able to achieve or maintain profitability.

Cash Flows

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

	Three Months Ended March 31,	
	2026	2025
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (19,234)	$ (23,112)
Investing activities	(11)	22,302
Financing activities	(415)	50,259
Net change in cash, cash equivalents and restricted cash	$ (19,660)	$ 49,449

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2026 was $19.2 million, which consisted primarily of a net loss of $19.3 million and a net change in operating assets and liabilities of $4.6 million, partially offset by $4.6 million in non-cash charges. The change in net operating assets and liabilities was primarily due to a decrease in accounts payable and accrued expenses and other current liabilities of $4.1 million. Cash flows from operations are generally impacted by the timing of payments to vendors and vendor payment terms. The non-cash charges primarily consisted of stock-based compensation of $2.2 million and depreciation and amortization of $1.8 million.

Net cash used in operating activities for the three months ended March 31, 2025 was $23.1 million, which consisted primarily of a net loss of $26.9 million and a net change in operating assets and liabilities of $3.4 million, partially offset by $6.9 million in non-cash charges. The change in net operating assets and liabilities was primarily due to a decrease in accounts payable and accrued expenses and other current liabilities of $2.3 million and a decrease in operating lease liabilities of $0.7 million, an increase in prepaid expenses and other current assets of $0.5 million. Cash flows from operations are generally impacted by the timing of payments to vendors and vendor payment terms. The non-cash charges primarily consisted of stock-based compensation of $3.7 million and depreciation and amortization of $2.7 million.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2026 was immaterial and consisted of purchases of property and equipment.

Net cash provided by investing activities for the three months ended March 31, 2025 was $22.2 million, which consisted primarily of proceeds from maturities of marketable securities of $11.7 million and sales of marketable securities of $11.0 million.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2026 was approximately $0.4 million, which consisted of payments of accrued offering costs.

Net cash provided by financing activities for the three months ended March 31, 2025 was $50.3 million, which primarily consisted of net proceeds from our March 2025 follow-on offering of $49.3 million.

Contractual Obligations and Other Commitments

There have been no material changes from the contractual obligations and commitments previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2025.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

A summary of our critical accounting policies and estimates is presented in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2025. There were no material changes to our critical accounting policies and estimates during the three months ended March 31, 2026.

Recent Accounting Pronouncements

See Note 2, *Summary of Significant Accounting Policies*, to our unaudited interim condensed financial statements for more information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition or results of operations.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the JOBS Act. We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (ii) the date we qualify as a “large accelerated filer,” with at least $700 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) December 31, 2026.

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, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to use the extended transition period to enable us to comply

with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date on which we (i) are no longer an emerging growth company and (ii) affirmatively and irrevocably opt out of the extended transition period provided by the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a smaller reporting company, meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million.

If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities Exchange Act of 1934 and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer, who is also serving as our interim Principal Financial Officer, has evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and interim Principal Financial Officer has concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and interim Principal Financial Officer, to allow timely decisions regarding required disclosure. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended March 31, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

A control system, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business. We are not currently a party to any litigation or legal proceedings that are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this quarterly report and in our other public filings in evaluating our business. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

Risk Factors Summary

Our ability to execute on our business strategy is subject to a number of risks and uncertainties, including those outside of our control, that could cause our actual results to be harmed, including risks regarding the following:

- We are early in our development efforts, with a limited operating history, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and future viability.
- We have not generated any product revenue to date, have incurred significant net losses since our inception, and expect to continue to incur significant net losses for the foreseeable future.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates, if approved.
- We require substantial additional capital to finance our operations, which if available, may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- Our product candidates are in the early stages of development, and we have no products approved for commercial sale. If we are unable to successfully develop, receive regulatory approval for, manufacture and commercialize our product candidates, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed.
- We intend to identify and develop gene therapy product candidates based on novel technology, and because the regulatory landscape that governs any product candidates we may develop is rigorous, complex, uncertain and subject to change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop.
- The mechanisms of action of our product candidates are unproven, and we do not know whether we will be able to develop any drug of commercial value.
- Drug development involves a lengthy and expensive process with an uncertain outcome. The preclinical studies, clinical trials and post-marketing studies of our product candidates may not demonstrate safety and efficacy to the satisfaction of the FDA, European Medicines Agency (EMA) or other comparable foreign regulatory authorities or otherwise produce positive results and the results of preclinical studies and early clinical trials may not be predictive of future results. We may incur additional costs or

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

- Our product candidates may cause serious adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could delay or prevent regulatory approval, or market acceptance, or even if approval is received, require them to be taken off the market, include new safety warnings, contraindications or precautions, or otherwise limit their commercial potential or result in significant negative consequences.
- Due to the significant resources required for the development of product candidates, and depending on our ability to access capital, we must prioritize development of certain programs and product candidates. Moreover, we may expend our limited resources on programs or product candidates that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- Gene therapies are novel, complex and difficult to manufacture. We could experience production problems that result in delays in development or commercialization of our product candidates, limit the supply of our products, if approved, or otherwise seriously harm our business.
- The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval of our product candidates, we will be unable to generate product revenue, and our business will be substantially harmed.
- If we are unable to obtain, maintain, protect, defend and enforce patent and other intellectual property coverage for our technology and product candidates, our competitors could develop and commercialize technology and product candidates similar or identical to ours, and our ability to commercialize our technology and product candidates may be adversely affected.
- Our commercial success depends significantly on our ability to operate without infringing, misappropriating or otherwise violating the patents and other intellectual property and proprietary rights of third parties.
- We rely on third parties to conduct our preclinical studies and our clinical trials, and plan to rely on third parties to conduct such future drug development activities. These third parties may not perform satisfactorily, including failing to meet completion deadlines, or to comply with applicable regulatory requirements, which may harm our business.
- If we do not regain compliance with or continue to satisfy the Nasdaq continued listing requirements, our common stock could be delisted from Nasdaq. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.

Risks Related to Our Financial Position, Need for Additional Capital and Limited Operating History

We are early in our development efforts, with a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and future viability.

We have limited experience conducting clinical trials, have no products approved for commercial sale and have not generated any revenue. We are developing therapies that address the underlying drivers of heart disease, which is an unproven and highly uncertain undertaking and involves a substantial degree of risk. Since our inception, we have devoted substantially all of our focus and financial resources to identifying and developing product candidates, conducting preclinical studies and clinical trials, developing our internal capabilities, acquiring technology, organizing and recruiting management and technical staff, business planning, establishing our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully complete any late-stage clinical trials, obtain marketing approvals, manufacture a late stage clinical- or commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it

may be more difficult for investors to accurately predict our likelihood of success and viability than it would be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biotechnology companies in rapidly evolving fields. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have not generated any product revenue to date, have incurred significant net losses since our inception, and expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses since our inception, have not generated any product revenue to date and have financed our operations principally through issuances of our stock. As of March 31, 2026, we had an accumulated deficit of $624.3 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs, manufacturing activities and from general and administrative costs associated with our operations. Our product candidates will require substantial additional development time and resources before we will be able to apply for regulatory approvals and, if approved, begin generating revenue from product sales. As a result, we expect that it will be several years, if ever, before we receive approval to commercialize a product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance, particularly since we expect our expenses to increase if and when our product candidates progress through late-stage clinical development, where costs may increase significantly. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our stock.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates, if approved.

Our business depends on the successful research, development, manufacturing, regulatory approval and commercialization of product candidates that we discover. Our ability to generate revenue and achieve profitability depends significantly on our ability, or any future collaborator's ability, to achieve several objectives, including:

- successful and timely completion of preclinical and clinical development of product candidates and programs, including, but not limited to, generating sufficient data to support the initiation or continuation of clinical trials;
- submission of INDs or other regulatory applications for our planned clinical trials, obtaining regulatory approval to commence clinical trials of our product candidates, and achieving favorable results from clinical trials;
- establishing and maintaining relationships with contract research organizations (CROs) and clinical sites for the clinical development of our product candidates;
- the initiation and successful patient enrollment and completion of clinical trials on a timely basis;
- acceptable frequency and severity of adverse events in the clinical trials;
- efficacy and safety profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;

- complying with any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for our product candidates, and the timely manufacture of sufficient quantities of a product candidate for use in clinical trials and, if approved, commercialization;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- the achievement of development, regulatory and sales-based milestones under our collaboration agreement with Alnylam;
- successful outputs from our capsid engineering and promoter and regulatory elements efforts;
- a continued acceptable safety profile following any marketing approval of our product candidates;
- actual market-size, ability to identify patients and the demographics of patients eligible for our product candidates, which may be different than expected;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- our ability to distribute our products to certain segments of the patient population only accessible through restricted or closed distribution channels;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- maintaining consistent quality, purity, and potency across clinical supplies and commercial supplies for any approved products;
- identifying, assessing and developing new product candidates, and our ability to expand into multiple indications;
- obtaining, maintaining, and expanding patent and other intellectual property protection, trade secret protection and regulatory exclusivity, both in the U.S. and internationally;
- protecting and enforcing our rights in our intellectual property portfolio;
- defending against third-party infringement, misappropriation, or other claims, if any;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates and to meet our obligations set forth under such arrangements;
- obtaining coverage and adequate reimbursement by third-party payors for our products and patients' willingness to pay in the absence of such coverage and adequate reimbursement;
- obtaining additional funding to develop, manufacture and commercialize our product candidates;
- addressing any competing therapies and technological and market developments;
- managing costs, including any unforeseen costs, that we may incur as a result of nonclinical study or clinical trial delays; and
- attracting, hiring and retaining qualified and key personnel including clinical, scientific, management and administrative personnel.

We may never be successful in achieving our objectives and, even if we are, may never generate revenue that is significant or large 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. Our failure to become and remain profitable would decrease our

value and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

We require substantial additional capital to finance our operations, which, if available, may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase over the long-term in connection with our ongoing activities, particularly as we initiate and conduct clinical trials of, and seek marketing approval for, our product candidates. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, EMA or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned preclinical studies and clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. We also expect to incur costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of March 31, 2026, we had $80.9 million in cash and cash equivalents. We may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our preclinical development programs, platforms, manufacturing activities, ongoing or planned clinical trials or future commercialization efforts.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, maintaining certain leverage ratios, making acquisitions, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or intellectual property, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. For example, under our collaboration agreement with Alnylam, we are not permitted to conduct any research or development activities with respect to certain collaboration targets or any therapeutic products designed to be directed to such targets, for as long as the target remains a collaboration target. If we are unable to raise additional funds through equity or debt financings, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our Loan Agreement requires us to comply with specified operating covenants and places restrictions on our operating and financial flexibility.

As of the filing date of this periodic report, under our Loan Agreement, we have the right to draw down up to $20.0 million, subject to agreement on the terms and conditions thereof and SVB's sole discretion. As security for our obligations under the Loan Agreement, we granted SVB a first priority security interest on substantially all of

our assets (other than intellectual property), subject to certain exceptions. We intend to satisfy our future debt service obligations with our existing cash and cash equivalents. However, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our outstanding debt. Funds from external sources may not be available on acceptable terms, if at all.

The Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict our ability to, among other things, dispose of assets, make changes to our business, merge or consolidate, incur additional indebtedness, incur additional liens, pay dividends or other distributions or repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain exceptions. These restrictive covenants could limit our flexibility in operating our business and our ability to pursue business opportunities that we or our stockholders may consider beneficial. In addition, a failure to comply with the conditions of our Loan Agreement, including a breach of any covenant, could limit our ability to draw upon available tranches or result in an event of default and an acceleration of any outstanding loans thereunder.

In the event of an acceleration of amounts due under our Loan Agreement as a result of an event of default, including upon the occurrence of an event or circumstance that could be expected to have a material adverse effect on our business, operations, properties, assets or financial condition or a failure to pay any principal or interest due, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and SVB could seek to enforce security interests in the collateral securing such indebtedness. Even if we are able to repay such accelerated debt amount under the Loan Agreement, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned. As such, any declaration by SVB of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. Further, if we are liquidated, SVB's rights to repayment under the Loan Agreement would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited.

Our net operating loss (NOL) carryforwards may be unavailable to offset future taxable income because of restrictions on their use under U.S. tax law. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in the corporation's ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change taxable income may be limited. Similar rules may apply under state tax laws. We have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. In addition, the use of our NOLs and other tax attributes may be subject to other limitations under applicable law. For example, California has enacted a temporary suspension on the use of state NOLs in taxable years beginning in 2024, 2025 and 2026, which would adversely affect our company if we earn taxable income in 2026. Consequently, our ability to use our NOLs and certain other tax attributes may be limited.

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

Our product candidates are in the early stages of development, and we have no products approved for commercial sale. If we are unable to successfully develop, receive regulatory approval for, manufacture and commercialize our product candidates, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed.

Before we are able to generate any revenue from product sales, each of our programs and product candidates will require additional preclinical and/or clinical development, expansion of manufacturing capabilities and expertise or successfully outsourcing manufacturing, regulatory approval, building a commercial organization or successfully outsourcing commercialization, substantial investment and significant marketing efforts. Consequently, because of the substantial operational and financial investment required to further develop and commercialize our product candidates, there is a high risk of failure and we may never succeed in developing marketable products.

If we do not successfully initiate and complete our clinical trials in a timely manner, including the successful manufacturing of the relevant product candidate, or fail to achieve favorable results from our trials, we may experience significant delays or be unable to advance our programs. We cannot be certain that our clinical trials will be initiated and completed on time, if at all, or whether our planned clinical strategy will be acceptable to the FDA or comparable foreign regulatory authorities. Furthermore, any changes to our development programs may cause our product candidates to perform differently and affect the results of planned clinical trials, which 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 commercialize our product candidates, if approved, and generate revenue.

There is a high failure rate for biopharmaceutical products proceeding through clinical trials. It is not uncommon for product candidates to exhibit unforeseen safety issues or inadequate efficacy when tested in humans despite promising results in preclinical animal models or earlier clinical studies. In addition, a number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage clinical trials and we may experience the same. We may also encounter regulatory delays or rejections as a result of many factors, including varying interpretations of data or changes in regulatory policy during the period of product development.

Because of the early stage of development of our programs, our ability to eventually generate significant revenues from our product candidates, which we do not expect will occur for several years, if ever, will depend on a number of factors, including those described in the Risk Factor entitled "*Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates, if approved*."

We do not have control over many of these factors, including certain aspects of the manufacturing process, preclinical and clinical development, the regulatory review process and potential threats to our intellectual property rights. If we are not successful with respect to one or more of these factors, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

To become and remain profitable, we must develop, obtain approval for and eventually commercialize product candidates that generate significant revenue. We do not expect to receive approval of any product candidates for many years and may never succeed in these activities. Even if we obtain approval and begin commercializing one or more of our product candidates, we may never generate revenue that is significant enough to achieve profitability, as we will continue to incur substantial research and development, manufacturing and other expenditures to develop and market additional product candidates. Even as we successfully discover and advance product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, manufacture, commercialize or generate significant revenue from any product candidates.

We intend to identify and develop gene therapy product candidates based on novel technology, and because the regulatory landscape that governs any product candidates we may develop is rigorous, complex, uncertain and subject to change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop.

We intend to discover, develop, manufacture, and commercialize gene therapy product candidates for the heart. Our product candidates may use both known capsids, such as AAV9, as well as proprietary capsids developed in-house through our own capsid engineering efforts or licensed from third parties. Furthermore, our product candidates may also use novel heart-specific promoters and we may explore different routes-of-administration involving infusion- or injection-based catheters to support targeted delivery and efficient uptake of gene therapies for the heart. We are also establishing proprietary manufacturing processes for our product candidates. Our future success depends on the successful development of these novel therapeutic approaches.

Within the broader genetic medicine field, very few therapeutic products, including those that utilize AAV-mediated gene transfer, have received marketing authorization from the FDA, EMA or comparable foreign regulatory authorities. No AAV-based gene therapies have yet been approved for the heart, much less therapies for the heart using novel capsids or promoters or delivery methods. It is therefore difficult to determine how long it will take, how much it will cost, or how likely it will be to obtain regulatory approvals for our product candidates in the U.S., EU or other jurisdictions.

The regulatory requirements that will govern any novel gene therapy product candidate we develop are not entirely clear, have changed over time and are subject to further change. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. Changes in the regulatory authorities' data requirements and risk mitigation methods, including requirements resulting from safety concerns raised by regulatory authorities in clinical programs of unrelated companies in the gene therapy and cardiovascular fields in general, could have a material impact on our clinical development, increase our costs, and delay or preclude regulatory approval of our product candidates. Moreover, there is substantial overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the U.S., the FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research (CBER) to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review.

Our product candidates will need to meet safety and efficacy standards applicable to any new biologic under the regulatory framework administered by the FDA. In addition to FDA oversight and oversight by investigational review boards (IRBs), under guidelines promulgated by the National Institutes of Health (NIH), gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee (IBC), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many clinical study sites receive NIH funding and many companies and other institutions not otherwise subject to the NIH guidelines voluntarily follow them. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

The same applies in the EU. The EMA's Committee for Advanced Therapies (CAT) is responsible for assessing the quality, safety, and efficacy of advanced-therapy medicinal products. Advanced-therapy medicinal products include gene therapy medicines, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the EMA. In the EU, the development and evaluation of a gene therapy product must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy products and require that we comply with these new guidelines. As a result, the procedures and standards applied to gene therapy products and cell therapy products in the EU may be applied to any gene therapy product candidate we may develop, but that remains uncertain at this point. Furthermore, approvals by the EMA may not be indicative of what the FDA may require for approval.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approvals necessary to bring a potential gene therapy product to market could decrease our ability to generate sufficient product revenue and our business, financial condition, results of operations and prospects could be materially harmed.

Adverse developments in preclinical studies or clinical trials conducted by others in the field of gene therapy and gene regulation products may cause the FDA, EMA, and other regulatory bodies to revise the requirements for the conduct of the clinical trials and approval of our product candidates or limit the use of products utilizing gene regulation technologies, either of which could harm our business. For example, the FDA has imposed clinical holds on various clinical trials of gene therapy product candidates being developed by other companies. In addition, the clinical trial requirements of the FDA, EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Further, as we are developing novel potential treatments for diseases in which, in some cases, there is little clinical experience with potential new endpoints and methodologies, there is heightened risk that the FDA, EMA or other regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. In addition, we may not be able to identify or develop appropriate animal disease models to enable or support planned clinical development. Any natural history studies that we may conduct or rely upon in our clinical development may not be accepted by the FDA, EMA or other regulatory authorities. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing gene regulation technology in a timely manner or under technically or commercially feasible conditions. In

addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting products. Further, approvals by one regulatory agency may not be indicative of what other regulatory agencies may require for approval.

The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop our product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our product candidates in a timely manner, if at all.

The mechanisms of action of our product candidates are unproven, and we do not know whether we will be able to develop any drug of commercial value.

We have discovered and are developing product candidates that have what we believe are novel mechanisms of action. Because no currently-approved drugs appear to operate via the same biochemical mechanisms as our compounds, we cannot be certain that our product candidates will result in commercially viable drugs that safely and effectively treat the indications for which we intend to develop them. The results we see for our compounds in preclinical models may not be replicated in subsequent preclinical studies or translate into similar results in humans in clinical trials, and results of early clinical trials in humans may not be predictive of the results of larger clinical trials or post-marketing studies that may later be conducted with our product candidates. As an example, patients may develop antibodies against the product candidates, or the product candidates may otherwise have a more limited duration of therapeutic effect than anticipated, resulting in decreased efficacy over time, which could delay approval and, if approved, limit the ultimate commercial value. Even if we are successful in developing and receiving regulatory approval for a product candidate for the treatment of a particular disease, we cannot be certain that it will be accepted by prescribers or be reimbursed by insurers or that we will also be able to develop and receive regulatory approval for that or other product candidates for the treatment of other diseases. If we are unable to successfully develop and commercialize our product candidates, our business will be materially harmed.

Moreover, in the event any of our competitors were to develop their own product candidates that have a similar mechanism of action to any of our product candidates, any efficacy or safety concerns identified during the development of such similar product candidates may have an adverse impact on the development of our product candidates. For example, if our competitors' product candidate having a similar mechanism of action as any of our product candidates is shown in clinical trials to give rise to serious safety concerns or have poor efficacy when administered to the target patient population, the FDA or other regulatory bodies may subject our product candidates to increased scrutiny, leading to additional delays in development and potentially decreasing the chance of ultimate approval of our product candidates.

Drug development involves a lengthy and expensive process with an uncertain outcome. The preclinical studies, clinical trials and post-marketing studies of our product candidates may not demonstrate safety and efficacy to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities or otherwise produce positive results and the results of preclinical studies and early clinical trials may not be predictive of future results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. We cannot guarantee that any of our preclinical studies or clinical trials will be initiated, conducted or completed on schedule or as planned, or at all. Failure can occur at any stage of testing. Such failure may result from a multitude of factors, including, among other things, flaws in study design, dose selection issues, placebo effects, patient enrollment criteria, novel assay design and failure to demonstrate favorable safety or efficacy traits, which could delay or prevent the submission of an IND or clinical trial application, initiation of a clinical trial, receipt of marketing approval or our ability to commercialize our product candidates, or require us to suspended or terminate further development of our product candidates. Moreover, the

outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. For example, our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. As a result, we cannot assure you that any preclinical studies, clinical trials or post-marketing studies that we conduct will demonstrate consistent or adequate efficacy and safety to support marketing approval.

Further, FDA and other regulatory authorities may implement new policies and regulations on clinical trials. For example, the EU Clinical Trials Regulation (CTR), which repealed the EU Clinical Trials Directive, became applicable on January 31, 2022, and provided a three-year transition period. The CTR streamlined the processes for applying for authorization and supervision of clinical trials in the EU. From January 31, 2025, any trials approved under the Clinical Trials Directive that continue running will need to comply with the CTR, and their sponsors must enter information on the trials in the Clinical Trials Information System. Trials we initiate in the United Kingdom are also subject to regulatory requirements and policies of the MHRA. Compliance with the CTR and/or MHRA requirements by us, our collaborators and third-party service providers, such as CROs, may increase our clinical trial costs and impact the timeline of our development plans. If we are slow or unable to adapt to changes in clinical trial requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be negatively impacted.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. This is particularly true for clinical trials in very rare diseases, such as with certain indications we are pursuing, where the very small patient population makes it difficult or impossible to conduct two traditional, adequate and well-controlled studies, and therefore the FDA or comparable foreign regulatory authorities are often permitted to exercise flexibility in approving therapies for such diseases. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Furthermore, the failure of any of our product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates and/or cause the FDA or comparable regulatory authorities to require additional testing before approving any of our product candidates.

We may experience numerous unforeseen events during, or as a result of, preclinical studies, clinical trials or post-marketing studies that could delay or prevent receipt of marketing approval or our ability to commercialize our product candidates, including:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- receipt of feedback from regulatory authorities that requires us to modify the design of our preclinical or clinical trials;
- preclinical study or clinical trial observations or results that require us to modify the design of our clinical trials;
- negative or inconclusive preclinical study or clinical trial results that may require us to conduct additional preclinical studies or clinical trials or abandon certain research and/or drug development programs;
- extended IRB, IBC and/or EC review process, or inability to obtain approval from one or more of these committees;

- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated, participants dropping out of these clinical trials at a higher rate than anticipated, or more patients failing to meet eligibility criteria than anticipated;
- any failure or delay in reaching an agreement with CROs and clinical trial sites;
- the suspension or termination of our clinical trials, as a result of a clinical hold by regulatory authorities or a voluntary pause, for various reasons, such as we experienced with MyPEAK-1;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- the costs and/or duration of preclinical studies or clinical trials being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate or slower than anticipated;
- subjects experiencing serious, severe, unexpected or otherwise important drug-related or study-related adverse effects;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- inaccurate or untimely clinical data collection, entry, analysis or reporting by clinical sites, third-party contractors and/or CROs;
- variability of efficacy assessments;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMPs, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCP or other regulatory requirements;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications;
- regulators revising the requirements for approving our product candidates;
- an unsuccessful post-marketing study or failure to complete such a study;
- absence in some countries of established groups with sufficient regulatory expertise for review of AAV gene therapy protocols; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

To the extent we pursue any pediatric indications or expand any approved drug product labeling to include pediatric populations, we may face additional challenges associated with clinical testing in pediatric populations, which can increase our operational costs, delay regulatory approval and commercialization, or expose us to additional liability. For example, finding qualified clinical sites that have access to sufficient pediatric populations and that are interested in participating in our clinical trials may take more time than adult indications. There may be fewer eligible patients with the target genetic disorder or heart disease or condition applicable to our product candidate for our planned clinical trials. This may increase the time needed to enroll patients for our planned pediatric clinical trials, increase our clinical development timelines, delay approval for such pediatric indications, and increase our operational costs. We may also be required to modify the formulation or other aspects of the

product candidate, as compared to the comparable product candidate intended for adult patient populations, make manufacturing changes, modify route of administration, and conduct additional clinical trials, such as bridging studies and additional safety studies before we can commence our clinical trials in pediatric populations. The FDA or other health authorities may require us to complete studies in adults prior to initiating testing in children. Any delays in our planned clinical development activities for pediatric patients could have an adverse effect on our business operations.

If we are required to conduct additional preclinical studies or clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete preclinical studies or clinical trials of our product candidates or other testing in a timely manner and if the results of these studies, trials or tests are not positive or are only modestly positive or if there are safety concerns, we may incur unplanned costs and be delayed in submitting an IND, initiating clinical trials or seeking and obtaining marketing approval. We may also decide to change the design or protocol of one or more of our planned clinical trials, which could result in increased costs and expenses and/or delays. Any delays in initiating or completing our preclinical studies or clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues, including by shortening any period during which we may have the exclusive right to commercialize our product candidates and permitting our competitors to bring products to market before we do. If we receive approval, it is possible that we may receive limited or restrictive marketing approval, be subject to additional post-marketing testing requirements or have the drug removed from the market after obtaining marketing approval.

Moreover, in the future, 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 interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates, which may harm our business, financial condition and prospects significantly.

Our product candidates may cause serious adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could delay or prevent regulatory approval or market acceptance, or even if approval is received, require them to be taken off the market, include new safety warnings, contraindications or precautions, or otherwise limit their commercial potential or result in significant negative consequences.

We are developing novel therapies for the treatment of heart disease. As a result, there is uncertainty as to the safety profile of product candidates we may develop. Patients in our clinical trials have suffered and may continue to suffer adverse events, including serious adverse events or other side effects, including those not observed in our preclinical studies or previous clinical trials. Patients treated with our product candidates may also be undergoing other therapies or procedures which can cause side effects or adverse events that are unrelated to our product candidates but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events, either during the course of or after participating in such trials. These events may be due to one or more factors, including, without limitation, the underlying heart disease, other therapies or medications that such patients may be using, the drug product formulation of our product candidates, complications arising from protocol regimens, the method of delivery of our product candidates or other diseases the patients have. In some cases, it may not be clear if an adverse event is due to the product candidate, another therapy, the underlying disease, or another cause, and causality may be incorrectly attributed to the product candidate.

Serious adverse events or other side effects observed in any of our clinical trials, through our expanded access program, or in similar trials by other sponsors, may result in difficulty recruiting patients to the clinical trials, cause patients to drop out of our trials, or require that we abandon the trials or our development efforts of that product candidate altogether.

We, the FDA, EMA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects or that the expected benefit does not justify the risk. For example, in November 2025, we announced that the FDA placed MyPEAK-1 on clinical hold to request a protocol amendment, primarily to standardize activities related to patient monitoring and management of the immunosuppressive regimen across trial sites. While the hold was lifted after swift and collaborative engagement with the FDA, there is no assurance that it or any future hold on our clinical trials would not have a material adverse effect on our business or our data milestones or development timelines for TN-201 or other product candidates.

Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. There is no guarantee that our product candidates will not have side effects similar to those seen in other gene therapies or that we will be able to prevent such side effects from escalating to an unsafe level for our patients. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies, result in marketing approval with restrictive label warnings or for limited patient populations, or result in potential product liability claims. Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. No regulatory agency has made any determination that any of our product candidates or discovery programs is safe or effective for use by the general public for any indication. We cannot predict whether our product candidates will cause toxicities in humans that would preclude regulatory approval, or if approved, lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future clinical trials will be successful. For instance, we do not know whether any of our product candidates will perform in our current or future preclinical studies or future clinical trials as it has in prior preclinical studies or earlier clinical trials. Product candidates in clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA and other comparable foreign regulatory authorities despite having progressed through preclinical studies. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates, or prevent regulatory approval.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing other therapies and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes and success in one trial does not ensure success in the next.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates.

If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion. Patient enrollment and retention are significant factors in the timing of clinical trials and our ability to enroll eligible patients may be limited or slower than we anticipate.

We are developing product candidates for the treatment of heart disease, including for certain indications, such as rare genetic diseases, that have limited patient pools from which to draw for clinical trials. We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for our planned clinical trials and monitoring such subjects adequately during and after treatment. The process of finding and diagnosing patients may prove costly. Further, the treating physicians in our clinical trials may also use their medical discretion in advising patients enrolled in our clinical trials to withdraw from our studies to try alternative therapies. Patients also have the right to withdraw from our clinical trials for any reason. Enrollment may also be impacted by an IRB or ethics committee decision to pause or stop enrollment at a trial site, a DSMB recommendation to pause or stop trial enrollment, or a decision by a regulatory authority to pause or stop trial enrollment in a particular country. Additionally, the FDA, EMA or other comparable foreign regulatory authorities may require long-term follow-up assessments for a certain number of patients, which could delay marketing approval.

We also expect patient enrollment to be affected because our competitors have ongoing clinical trials for programs that are under development or are approved for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials could instead enroll in clinical trials of our competitors' programs or choose to take an approved medication. Patient enrollment for our clinical trials has been and may continue to be affected by other factors, including:

- size and nature of the patient population;
- the perceived risks and benefits of novel, unproven approaches;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- ongoing clinical trials evaluating other product candidates in the same disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- regulatory actions, ongoing IRB and/or ethics committee decisions and DSMB recommendations;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or other product candidates being investigated for the indications we are investigating;
- public perception about the use of genetic medicines in human therapeutics or precision medicine;
- patient referral practices of physicians;
- challenges associated with recruiting eligible patients;
- the ability to monitor patients adequately during and after treatment;
- limited staff and resources at clinical trial sites, including support for clinical trial enrollment and the availability of hospital beds;
- the activities of key opinion leaders (KOLs) and patient advocacy groups;
- proximity and availability of clinical trial sites for prospective patients and the ability of patients to travel to these sites;

- the practical and financial burden of the trial protocol on patients, including conflicts with their work, family and personal activities, as well as travel costs, lodging, lost wages and insufficient reimbursement or support;
- delays in site activation, contracting and budget approvals;
- protocol amendments, reviews and approvals;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may have an advanced disease, will not survive the full terms of the clinical trials; and
- limitations on the rate of patient enrollment required by the clinical trial protocol, including those that may be requested by health authorities.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

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

Due to the significant resources required for the development of product candidates, in particular our product candidates in clinical trials, we must decide which programs, product candidates and indications to pursue and advance the amount of resources to allocate to each. For example, in connection with our cost containment measures, we are prioritizing generating data from our MyPEAK-1 and RIDGE-1 clinical trials of TN-201 and TN-401, respectively. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular programs, product candidates or therapeutic areas may not lead to the development of any viable commercial product and may result in the diversion of resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain platforms, programs or product candidates may subsequently also prove to be less than optimal and could cause us to miss valuable opportunities. If we make incorrect assumptions and/or determinations regarding data emerging from our clinical trials, the viability or market potential of any of our programs or product candidates or misread trends in the biotechnology industry, in particular in the field of cardiology, our business could be seriously harmed. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other programs, product candidates or other diseases that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to our platforms or product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

We face significant competition and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates.

We have competitors both in the U.S. and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, universities and other research institutions. We face competition in recruiting personnel, establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates.

We expect to face competition from existing products and products in development for each of our programs and anticipate substantial direct competition from a variety of competitors. Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in our field before we do.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for their products 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. Due to the nature of gene therapy products, use of a competitor gene therapy product by a prospective patient may preclude use of our gene therapy product candidate at a later point in time. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

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

From time to time, we may publicly disclose initial, interim or topline data from our clinical trials. These updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following availability of additional data and a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the initial, interim and/or topline results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Initial, interim and/or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, initial, interim and topline data should be viewed with caution until the final data is available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Initial and interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between initial and/or interim data and final data could significantly harm our business and prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, may do their own analyses, or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to

publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the initial, interim or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

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

Our gene therapy product candidates require processing steps that are more complex than those required for most chemical and protein pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as ours generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, we need to employ multiple steps to control our manufacturing process to ensure that the process works and the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, including during the manufacture of drug substance, drug product, filling, labeling, packaging, storage, shipping, QC and testing and/or in connection with release assays, including potency assays, could result in product defects, lot failures, product recalls, product liability claims or insufficient inventory, and may ultimately disrupt or delay the supply of our product candidates.

Although some of our employees have experience in the manufacturing of biopharmaceutical products from prior employment at other companies, we as a company have limited experience in manufacturing and oversight of CDMOs conducting manufacturing activities on our behalf. We may also encounter problems hiring and retaining the experienced personnel needed to manage our complex manufacturing operations, including those outsourced to CDMOs. If we experience unanticipated employee shortage or turnover in any of these areas, we may not be able to maintain oversight of our QC, conduct further process improvements or meet our product development timelines; we may also experience difficulties in maintaining compliance with applicable regulatory requirements, which would impair our product development and commercialization efforts.

To date, our product candidates have been manufactured in quantities adequate for preclinical studies and our Phase 1b/2 clinical trials for our lead product candidates. We will need to manufacture product candidates in larger quantities for commercialization of the resulting product, if that product candidate is approved for sale, and we may need to manufacture more product to conduct later-stage clinical trials. We may not be able to successfully repeat or increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner or at all. Significant changes or scale-up of manufacturing may require additional validation studies, which are costly and which regulatory authorities must review and approve. In addition, quality issues may arise during those changes or scale-up activities.

As product candidates progress through preclinical studies and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue. Moreover, if we choose to transfer manufacturing activities for our clinical-stage gene therapy programs to a CDMO, we may also be required to conduct additional studies to ensure comparability, notify and submit additional filings to regulatory authorities, and obtain regulatory authority approval for the new facilities, which may be delayed or never received. While the manufacturing process alone is complex, quality issues may also arise during drug product filling, labeling, packaging, storage, shipping and ongoing QC and testing activities.

If we are unable to successfully manufacture any of our product candidates in sufficient quality and quantity, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed or there may be a shortage in supply, which could significantly harm our business.

The manufacture of our product candidates will be subject to significant government regulations and approvals, which are often costly and could result in adverse consequences to our business if we or our CDMO's fail to comply with the regulations or maintain the approvals.

We will need to comply with the FDA's and applicable foreign regulatory authorities' cGMP requirements for the production of product candidates for clinical trials and, if approved, commercial supply. We and our CDMOs will be subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. These requirements include the qualification and validation of manufacturing equipment and processes. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture of our product candidates as a result of a failure of our facilities or the facilities or operations of our CDMOs or third-party suppliers to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our product candidates for our clinical trials or the termination or hold on a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non-compliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution. Furthermore, regulatory requirements for the manufacturing of genetic medicines may change over time. Our failure to comply with such changes could have a material impact on the manufacturing costs for our product candidates, delay our planned preclinical and clinical trial timelines and/or preclude regulatory approval of our product candidates.

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors and others in the medical community. If we are unable to demonstrate sufficient safety or efficacy to permit a broader use of our product candidates, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- perceived safety and efficacy profile and ease of use for pediatric patient population if approved for a pediatric indication;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a risk evaluation and mitigation strategy, if any, which may not be required of alternative treatments and competitor products;
- physicians, hospitals, treatment centers and patients considering our product candidates a safe, pure and effective treatment;
- the perceived prevalence and severity of any side effects for our product candidates compared to the prevalence and severity of any side effects for conventional products and other gene therapies;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- relative convenience and ease of administration;
- the willingness of the target patient population or their caregivers to try new therapies and of physicians to prescribe these therapies;

- the size of the relevant pediatric patient population if approved for a pediatric indication, including challenges associated with diagnosing or identifying pediatric populations with the applicable target disease or condition;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- patients' willingness to pay for these therapies in the absence of such coverage and adequate reimbursement;
- the effectiveness of sales and marketing efforts;
- support from KOLs and patient advocacy groups;
- negative public perception about the use of genetic medicines, whether related to our technology or our competitor's technology;
- unfavorable publicity relating to our product candidates;
- the approval of other new therapies for the same indications; and
- the acceptance and use of genetic testing required to diagnose the disease and identify patients who qualify for treatment with our product candidates.

If any of our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

The limited number of patients who have the diseases for which our product candidates are being developed may make it more difficult for us to enroll or complete clinical trials or may result in findings in our clinical trials that do not reach levels of statistical significance sufficient for marketing approval. Even if such product candidates achieve marketing approval, because such target patient populations are small and the addressable patient population may be even smaller, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth.

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

Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, because the potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. The indications we are initially pursuing for our gene therapy product candidates have small patient populations. For product candidates that are designed to treat smaller patient populations to be commercially viable, the reimbursement for such product candidates must be higher, on a relative basis, to account for the lack of volume. Accordingly, we will need to implement a coverage and reimbursement strategy for any approved product candidate that accounts for the smaller potential market size.

Sales of any of our product candidates that receive marketing approval will depend substantially, both in the U.S. and internationally, on the extent to which the costs of such product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the U.S., for example, principal decisions about reimbursement for new products are typically made by CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate or at the same level of reimbursement. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the U.S., the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the EU, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. 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 therapies. In general, product prices under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for 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 U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage, such inability could have an adverse effect on our business and financial condition. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. We have limited product liability insurance. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. As clinical trial and product liability insurance becomes increasingly expensive, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition. Also, our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We may be sued if any of our product candidates or any medications, procedures or activities associated with our clinical trial protocols or our expanded access program cause or are perceived to cause injury, or if our product candidates are found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale post-approval. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the protocol or product, negligence, strict liability, or a breach of warranties. Claims could also be asserted under state consumer protection laws. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our products. Even a successful defense would require significant financial and management resources.

Regardless of the merits or eventual outcome, liability claims may result in:

- delays in the development of our product candidates;
- FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and the facilities used to manufacture our products or our marketing programs;
- decreased or interrupted demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing, or promotional restrictions;
- loss of revenue;
- inability to raise capital or enter into strategic agreements for the development of our product candidates;
- exhaustion of any available insurance and our capital resources; and

- the inability to commercialize any products.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

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

Our product candidates are and will continue to be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing, distribution and orphan exclusivity of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the U.S. and in many foreign jurisdictions before a new drug can be approved for marketing. Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is costly, unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved and the availability of alternative therapies. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data.

We cannot provide assurance that any of the product candidates we develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them. Applications for our product candidates could be delayed or fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may refuse to accept an application or decide not to accept data from our clinical trials conducted in locations outside of their jurisdiction;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may require that we conduct additional preclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that our product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of CDMOs and or third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve companion diagnostic tests required for commercialization of our product candidates; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

business, results of operations and prospects. Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from any particular product candidates we are developing and for which we are seeking approval.

Further, under the current leadership at the HHS, layoffs due to the reduction in force initiative and other measures implemented by the Department of Government Efficiency, agency staff departures, and lapse of government appropriations can impact the normal operations of the FDA as well as other federal agencies. The FDA may lack adequate staff and resources to meet current review, approval, and inspection schedules, which could delay our anticipated timelines. It is unclear how our industry and our clinical programs will be impacted by policies, regulations and initiatives implemented under the current administration and FDA commissioner, or other executive orders. There is significant uncertainty in the industry and how federal agencies like the FDA will change in the coming years under the current administration. To the extent the agency reorganization and other agency changes lead to disruptions in FDA's operations, our correspondence and regulatory review processes with the FDA may be materially delayed.

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.

If the FDA or EMA grants marketing approval of a product candidate, other comparable regulatory authorities in foreign jurisdictions must still approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. A failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the U.S., 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 U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be harmed.

Even if our product candidates receive regulatory approval, such approval may be for a narrower indication than we seek, and our product candidates will be subject to significant post-marketing regulatory requirements and oversight.

Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product's commercial potential. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market, promote and advertise the drug or the labeling or other restrictions. The regulatory authorities may require precautions or contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy plan as part of approving an NDA or biologics license application, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially harm our business, financial condition, results of operations and prospects, and may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

In addition, if the FDA, EMA or other foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMP and GCP for any clinical trials that we conduct

post-approval. Manufacturers of drug products and the facilities where the products are manufactured are also subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue. Furthermore, non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

To the extent we obtain orphan drug and other designations from the FDA for our product candidates, we may not realize the full benefits of such designations. Further, orphan drug exclusivity may not prevent the FDA, EMA or other comparable foreign regulatory authorities, from approving competing products.

Regulatory authorities in some jurisdictions, including the U.S. and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. Similarly, in the EU, the EC, upon the recommendation of the EMA's Committee for Orphan Medicinal Products, grants orphan drug designation to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition. In the EU, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug.

In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the U.S. provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. In view of the court decision in the *Catalyst Pharms., Inc. v. Becerra*, 14

F.4th 1299 (11th Cir. 2021) case, in a January 2023 notice, the FDA clarified that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order. The Consolidated Appropriations Act of 2026, signed into law in February 2026, codified this longstanding FDA interpretation of the Orphan Drug Act, allowing the FDA to approve multiple versions of the same orphan drug for different subindications and subpopulations. The applicable exclusivity period for an orphan drug is ten years in the EU. The EU orphan exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Under the Rare Pediatric Disease Priority Review Voucher program, a sponsor who receives an approval for a drug or biological product for a rare pediatric disease may qualify for a voucher that can be redeemed to receive priority review for a different product. The sponsor may also transfer or sell the voucher to another sponsor. FDA awards rare pediatric disease priority review vouchers to sponsors of rare pediatric disease products that are approved and meet certain criteria, including a product candidate intended to treat a manifestation of a serious or life-threatening disease or condition in children aged 0 through 18 years of age. The rare pediatric disease priority review program has been extended by Congress through September 2029 under the Consolidated Appropriations Act, 2026, which means the FDA may not award any priority review vouchers under this program after September 30, 2029. There is no guarantee that any of our product candidates will be approved by that date, or at all. We may not obtain a priority review voucher prior to expiration of the program, unless Congress further reauthorizes the program.

Our lead product candidates from our gene therapy platform, TN-201 and TN-401, have each been granted orphan drug designation by the FDA and the EC, and we may seek orphan drug designation for other product candidates in the U.S., Europe and other jurisdictions. TN-201 has also received rare pediatric disease designation from the FDA for MYBPC3-associated HCM. We may not be able to maintain orphan drug exclusivity for our product candidates and may not realize all the benefits of the orphan drug designation and the rare pediatric disease designation. Receiving these designations does not change FDA's standards for regulatory approval of our product candidates and may not lead to faster regulatory review of any product candidate or increase the likelihood that any product candidate will receive marketing approval, if at all. We may seek orphan drug designation for other product candidates in the U.S., Europe and other jurisdictions, however, there can be no assurances that we will be able to obtain orphan drug designation for our other product candidates.

We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication, in which case we could be precluded from receiving marketing approval for our product candidate for the applicable exclusivity period. In addition, exclusive marketing rights in the U.S. may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to priority review.

We may face difficulties from changes to current FDA and healthcare regulations and future legislation.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the U.S. or abroad. For example, certain policies of the

current U.S. administration may impact our business and industry, which could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how current and future legislation, executive actions, and litigation, including the executive orders referenced below, will be implemented, and the extent to which they will impact our business, our clinical development, and the FDA's and other agencies' ability to exercise their regulatory authority, including FDA's pre-approval inspection and timely review of any regulatory filings or applications we submit to the FDA. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course or constraints on our business operations, including operations of our contractors, our business may be negatively impacted.

In June 2024, the U.S. Supreme Court overruled the Chevron doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. Further, under the new leadership at the HHS under the current U.S. presidential administration, agency reorganization, mass layoffs due to the reduction in force initiative and other measures implemented by the Department of Government Efficiency may impact the normal operations of the FDA as well as other federal agencies. The FDA may lack adequate staff and resources to meet current review, approval, and inspection schedules, which could delay our anticipated timelines. To the extent the agency reorganization and other agency changes lead to disruptions in FDA's operations, our correspondence and regulatory review processes with the FDA may be materially delayed.

The pharmaceutical industry in the U.S. has also been significantly impacted by other major legislative initiatives. Under the American Rescue Plan Act of 2021, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs was eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various stakeholders, including pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of Health and Human Services to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. In September and October 2025, the government announced the first agreements with two major pharmaceutical companies to bring American drug prices in line with the lowest paid by other developed nations, requiring the companies to offer medicines at a deep discount off the list price when selling directly to American patients. Such agreements and other government measures that use most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the United States, or increases generic and biosimilar drug entry sooner than expected, that can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future. We cannot predict the full impact of the executive orders focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chain and manufacturing in the United States. The impact of ongoing and future judicial challenges as well as future legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the current administration on us and the pharmaceutical industry as a whole is unclear. Further, changes to the leadership of federal agencies under the current administration, as well as new policies, executive orders and actions, such as a freeze on hiring, return-to-office policy, and a freeze on implementing new regulations and on external

communications, may impact normal operations of the FDA and other agencies or result in a material impact on our clinical development plans and timelines. The implementation of cost containment measures, including the prescription drug provisions under the IRA, as well as other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. 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.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We are subject to stringent laws, rules, regulations, policies, industry standards and contractual obligations regarding data privacy and security and may be subject to additional related laws and regulations in jurisdictions into which we expand. Many of these laws and regulations are subject to change and reinterpretation and could result in claims, changes to our business practices, monetary penalties, increased cost of operations or other harm to our business.

The regulatory framework for privacy and personal information security issues worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. The U.S. federal and various state, local and foreign government bodies and agencies have adopted or are considering adopting laws, rules, regulations and standards limiting, or laws, rules, regulations and standards regarding, the collection, distribution, use, disclosure, storage, transfer, security and other processing of personal information.

Outside of the U.S., we are subject to extensive legal requirements relating to privacy, data protection, security and the collection, distribution, use, disclosure, storage, transfer and other processing of personal data. For example, the collection and use of health data and other personal data, including personal data collected in clinical trials, is governed in the EU by the GDPR, which imposes substantial obligations upon companies and provides rights for individuals, and by certain EU member state-level legislation. The GDPR also forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (SI 2019/419), known as UK GDPR. Failure to comply with the GDPR or UK GDPR may result in fines up to €20,000,000 (£17.5 million in the UK) or 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. The GDPR or UK GDPR impose significant responsibility and expose us to potential liability in relation to personal data that we may process, and we may be required to implement additional measures in an effort to comply with the GDPR and UK GDPR or with other laws, rules, regulations and standards in the EEA, UK and Switzerland relating to privacy and data protection. This may be onerous and if our efforts to comply with GDPR and UK GDPR or other applicable laws, rules, regulations and standards are not successful, or are perceived to be unsuccessful, it could adversely affect our business. Further, restrictions on the transfer of personal data from the EEA, UK, Switzerland or other jurisdictions to the U.S. or other

regions, could restrict our activities in those jurisdictions, limit our ability to provide our products and services in those jurisdictions, require us to modify our policies and practices, and to engage in additional contractual negotiations, or increase our costs and obligations and impose limitations upon our ability to efficiently transfer personal data to the U.S. In Canada, the Personal Information Protection and Electronic Documents Act (PIPEDA) and similar provincial laws impose obligations on companies with respect to processing personal information, including health-related information, regarding Canadian data subjects and provides individuals certain rights with respect to such information, including the right to access and challenge the accuracy of their personal information held by an organization. Failure to comply with PIPEDA, where applicable, could result in fines and penalties.

In the U.S., a variety of laws, rules, regulations and standards relating to privacy, data protection, security, and the distribution, use, disclosure, storage, transfer and other processing of data potentially may apply to our activities, such as state data breach notification laws, state personal data privacy laws, for example, the CCPA, state health information privacy laws, and federal and state consumer protection laws. The CCPA requires covered businesses that process personal information of California residents to disclose their data collection, use, sharing and retention practices, provides California residents with data privacy rights (including the ability to opt out of certain disclosures of personal information including for certain advertising purposes), imposes operational requirements for covered businesses, provides for significant civil penalties for violations as well as a private right of action for certain data breaches and statutory damages (that is expected to increase data breach class action litigation and result in significant exposure to costly legal judgments and settlements). Although there are limited exemptions for clinical trial data under the CCPA and certain other state laws, the CCPA and other new and evolving state laws could impact our business activities, depending on their interpretation. Numerous other states have enacted laws relating to privacy and data security that either are in operation or slated to go into operation over the next several years. In many cases, these laws are comprehensive privacy laws similar to the CCPA, with potentially greater penalties and more rigorous compliance requirements.

States also are enacting laws addressing specific subject matter, such as Washington's My Health, My Data Act, which includes a private right of action. Laws in all 50 states may require businesses to provide notice to individuals whose personal data has been disclosed as a result of a data breach. The U.S. government also has instituted rules, effective April 8, 2025, that prohibit or restrict transactions involving certain types and amounts of sensitive data between U.S. persons and foreign persons associated with specific countries of concern. Among other things, these new rules require U.S. businesses to seek assurances from certain foreign parties with which they share sensitive data (under certain types of agreements) that those parties will not further share that data with parties in countries of concern. Finally, federal, state and foreign laws, rules, regulations and standards may apply generally to the privacy and security of information we maintain, and may differ from each other significantly, thus complicating compliance efforts and potentially requiring us to undertake additional measures to comply with them.

With the GDPR, PIPEDA, CCPA, and other laws, regulations and other obligations relating to privacy, data protection and security imposing new and relatively burdensome obligations, and with substantial uncertainty over the interpretation and application of these laws, regulations and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices, and may incur significant costs and expenses in an effort to do so.

We make public statements about our use, collection, disclosure and other processing of personal data through our privacy policies, information provided on our website and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. Any failure or perceived failure by us or our vendors or service providers to comply with our applicable policies or notices relating to privacy or data protection, our contractual or other obligations to third parties, or any of our other legal obligations, laws, rules, regulations and standards relating to privacy or data protection, may result in governmental investigations or enforcement actions, litigation, claims and other proceedings, harm our reputation, and could result in significant liability.

Our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to significant losses, including, among other things, criminal

sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

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

- the federal Anti-Kickback Statute which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the Civil Monetary Penalty Act of 1981 and implementing regulations, which impose penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offered or transferred remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on covered entities, which are health plans, healthcare clearinghouses, and certain health care providers, as those terms are defined by HIPAA, and their respective business associates and their subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as nurse practitioners and physician assistants, among others), and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to

physicians and other healthcare providers, marketing expenditures, or drug pricing; state and local laws that require the registration of pharmaceutical sales and medical representatives; state laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and data privacy and security laws and regulations will involve substantial ongoing costs and may require us to undertake or implement additional policies or measures. We may face claims and proceedings by private parties, and claims, investigations and other proceedings by governmental authorities, relating to allegations that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, and it is possible that courts or governmental authorities may conclude that we have not complied with them, or that we may find it necessary or appropriate to settle any such claims or other proceedings. In connection with any such claims, proceedings, or settlements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CDMOs, 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, CDMOs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended 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, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

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 our business.

We 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. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting

damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

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

Our business activities are subject to the U.S. Foreign Corrupt Practices Act and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our business activities are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended (FCPA), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. These laws generally prohibit companies and their employees and agents from offering or providing improper payments or benefits to recipients in the public or private sector. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA.

We sometimes leverage third parties to assist with the conduct of our business abroad. As we increase our international business activities, our risks under these laws may increase. We, our employees and agents may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities and may be held liable for the corrupt or other illegal activities of these employees and agents even if we do not explicitly authorize such activities.

These laws also require that we make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls and compliance procedures designed to prevent violations of anti-corruption laws. While we have policies and procedures to address compliance with such laws, we cannot assure you that all of our employees and agents will not take actions in violation of applicable law for which we may be ultimately held responsible.

Allegations or violations of these laws and regulations could result in whistleblower complaints, fines, severe civil or criminal sanctions, settlements, prosecution, enforcement actions, damages, adverse media coverage, investigations, loss of export privileges, disgorgement, and other remedial measures, suspension or debarment from government contracts and prohibitions on the conduct of our business including our ability to offer our products in one or more countries. Responding to any investigation or action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. As a general matter, investigations, enforcement actions and sanctions could damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

In addition, 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 sales and adversely affect our revenue. 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.

There is currently significant uncertainty about the future relationship between the U.S. and various other countries, most significantly China, with respect to trade restrictions, treaties, foreign investment laws, data transfer restrictions, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could introduce additional restrictions and negatively impact our business. For example, legislation in Congress known as the BIOSECURE Act was passed as part of the 2026 National Defense Authorization Act, which limits certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. Other new regulations could affect the transfer of certain types of data abroad, including to China, and may add expenses or unforeseen burdens to the process of contracting with service providers. These regulations, or similar laws and regulations in the future, could adversely impact our current or future third-party arrangements with certain companies, including those in China or Chinese-owned U.S. companies, which could delay or impact our clinical trials and consequently delay or obstruct successful commercialization of our product candidates. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

Increased tariffs on imports, trade sanctions, other trade restrictions, or a global trade war could increase our costs and materially and adversely affect our business operations and financial condition.

Our business could be negatively affected by tariffs, trade restrictions, and other governmental actions, any of which can be imposed suddenly and unpredictably. For example, there is currently significant uncertainty about the future relationship between the U.S. and various other countries with respect to trade policies, treaties, trade regulations, and tariffs. Beginning in 2025, the U.S. government imposed or announced various new tariffs on certain imports, including commodity-specific, reciprocal, and country-specific tariffs, and additional tariffs may be forthcoming. For example, in April 2025, the U.S. Department of Commerce initiated an investigation into potential tariffs on pharmaceuticals, pharmaceutical ingredients, and derivative products; when these investigations are complete, the U.S. government may decide to levy additional tariffs on these products. These or additional tariffs (and the uncertainty around their implementation) could affect inputs to our products, as well as equipment, materials, or components that we import into the U.S. from our suppliers, which could significantly impact the cost of these items. Retaliatory tariffs could also negatively affect our ability to export and sell our potential products into those countries. If these tariffs are implemented, reinstated or adjusted, if additional tariffs are placed, or if any related countermeasures are taken by the U.S. or other countries, our business, financial condition, and results of operations may be materially harmed.

Trade restrictions, tariffs, and other general economic or political conditions may limit our ability to obtain key materials, components, or equipment for our products or significantly increase supply chain costs and other expenses associated with our business, which could further materially and adversely affect our results of operations, financial condition, and prospects. The ultimate impact of any tariffs or trade restrictions will depend on various factors, including the timing of implementation and the duration, amount, scope, and nature of the tariffs and trade restrictions and reactions from other countries.

Tariffs, trade restrictions or any resulting trade war could negatively affect the global market, including for pharmaceuticals, and could have a significant adverse effect on our business, financial condition, and results of operations.

Changes in tax law could increase the tax burden on our orphan drug programs and adversely affect our business and financial condition.

Changes in tax law, including to the orphan drug tax credit and other changes to U.S. and non-U.S. taxation, could increase our tax liability and adversely affect our operating results. For example, starting from January 1, 2022, the Tax Cuts and Jobs Act of 2017 requires taxpayers to capitalize domestic research and development costs in the year incurred and amortize such costs rather than deduct such costs in the year incurred. On July 4, 2025, the U.S. federal tax legislation commonly referred to as the One Big Beautiful Bill Act (the OBBB Act) was enacted, which makes a number of changes to U.S. federal income tax law, including permanently suspending the

requirement to capitalize and amortize domestic research and development expenditures and permitting such deductions on a current basis. While we have reflected the effects of the enactment of OBBB Act for the fiscal year ended December 31, 2025, we will continue to evaluate the full impact of the legislation on us. These changes could affect our total U.S. federal tax liability when and if we become profitable.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

We are highly dependent on the principal members of our management, our scientific and clinical advisors and consultants, and our scientific and medical staff. If we do not succeed in attracting and retaining such personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We do not maintain "key person" insurance for any of our executives or other employees. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

Additionally, we rely on our scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. These advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting relationships with our scientific advisors and consultants or if they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be significantly harmed.

In order to successfully implement our long-term plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

In order to successfully implement our development and commercialization plans and strategies, we expect to need additional managerial, operational, sales, marketing, financial and other personnel in the future.

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

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of our research and development, clinical development, manufacturing and operations. We cannot assure you 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 or accuracy of the services provided by third-party service providers is compromised for any reason, our preclinical studies and the initiation and conduct of our planned clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our product candidates or otherwise advance our programs and business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If, subject to the successful clinical development of our product candidates, we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our computer systems, or those of any of our CROs, manufacturers, contractors, consultants or other third parties or potential future collaborators, may fail or suffer security incidents or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

As part of our business, we and our CROs, manufacturers, contractors (including sites performing our clinical trials), consultants and other third parties, collect, maintain and transmit sensitive data on our networks and systems, including our intellectual property and proprietary and confidential business information (such as research data and personal information). Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems, and those of our third-party CROs, manufacturers, contractors (including sites performing our clinical trials), consultants and other third parties, such systems are vulnerable to breakdown or other damage or interruption from, among other things, inadvertent or intentional actions by our employees, contractors, consultants, business partners, and other third parties and cyber-attacks and other hacking attempts by malicious third parties, which may disrupt or compromise our system infrastructure or lead to the loss, destruction, alteration, prevention of access to, disclosure, dissemination of, or damage or unauthorized access to, our data or other data that we process or maintain or that is processed or maintained on our behalf, or other assets. Although we have not observed material impacts of cyber-attacks on our operations and financial condition to date, we and our third-party service providers have frequently been the target of threats of this nature and we expect these threats and attacks to continue.

Any disruption or security breach or incident resulting in any loss, destruction, unavailability, alteration, disclosure or dissemination of, or damage or unauthorized access to, our data, or any other data that we maintain or otherwise process or that is maintained or otherwise processed on our behalf, or other assets, or for it to be believed or reported that any of the foregoing occurred, could cause us to incur significant liability, including consequential damages, financial harm and reputational damage and the delay of the development and commercialization of our product candidates. The loss, corruption, or unavailability of clinical trial data for our product candidates also could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. We cannot ensure that our data protection or cybersecurity efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties, will prevent breakdowns in our or their systems or have prevented, or will prevent, security breaches or incidents, including those that cause loss, destruction, unavailability, alteration, dissemination of, or damage or unauthorized access to, our data, including personal data, or other assets or other data processed or maintained on our behalf. Any such breakdowns, breaches, or incidents, and any resulting impacts, could have a material adverse effect upon our reputation, business, operations and financial condition.

We also rely on third parties to support the development and manufacture of our product candidates, and any security breaches or other incidents or other security events relating to their computer systems could also have a material adverse effect on our business. Controls employed by our information technology department and our CROs, consultants and other third parties could prove inadequate, and our ability to monitor such third parties' cybersecurity practices is limited. Due to applicable laws, rules, regulations and standards or contractual obligations, we may be held responsible for any cyber-attack, security breach or incident or cybersecurity failure attributed to our third-party service providers as relevant to the information they maintain or otherwise process for us. While we maintain cybersecurity insurance that we believe to be reasonable for our business, our current cybersecurity insurance may not fully cover the damages arising from the assertion of one or more large claims against us in connection with a breach or other cybersecurity-related matter, which could adversely affect our business, financial condition, results of operations and prospects.

Notifications and follow-up actions related to a data breach or other security incident could impact our reputation and cause us to incur significant costs, including significant legal expenses and remediation costs. We expect to incur significant costs in an effort to detect and prevent security breaches and other incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security

breach or other incident. However, we cannot guarantee that we will be able to detect or prevent any such breaches or incidents, or that we can identify, remediate or otherwise address any such breaches or incidents in an effective or timely manner. Our efforts to improve security and protect data from compromise may also identify previously undiscovered instances of data breaches or other cybersecurity incidents. Any disruption or security breach or incident resulting in any loss, destruction, or alteration of, or damage, unauthorized access to or inappropriate or unauthorized disclosure, dissemination or other processing of, our data, including personal data, or other information maintained or otherwise processed on our behalf, or any belief or reporting of any of these matters having occurred, could expose us to litigation and governmental investigations and inquiries, could lead to delays in the further development and commercialization of our product candidates, and could result in significant fines or penalties for any noncompliance with certain state, federal and international privacy and security laws, rules, regulations and standards.

Our operations are vulnerable to interruption by fire, earthquakes, power loss, telecommunications failure, terrorist activity, pandemics and other events beyond our control, which could harm our business.

Our facilities are located in the San Francisco Bay Area. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, flood, blizzard, wildfire, power loss, terrorist activity, pandemics or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. Also, our CDMOs and suppliers' facilities are located in multiple locations where other natural disasters or similar events which could severely disrupt our operations, could expose us to liability and could have a material adverse effect on our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

A variety of risks associated with development and marketing our product candidates internationally, subject to regulatory approval in applicable jurisdictions, could materially adversely affect our business.

We may seek regulatory approval of our product candidates outside of the U.S. and/or work with contractors or partners in foreign jurisdictions, and we expect that we will be subject to additional risks and requirements related to our operations in foreign countries, including:

- differing regulatory requirements and reimbursement regimes;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;
- challenges obtaining, maintaining, protecting, defending and enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain, protect, defend and enforce patent and other intellectual property coverage for our technology and product candidates, our competitors could develop and commercialize technology and product candidates similar or identical to ours, and our ability to commercialize our technology and product candidates may be adversely affected.

Our commercial success depends in large part on our ability to obtain, maintain, protect, defend and enforce patents, trade secrets and other intellectual property relating to our product candidates and platforms and to operate without infringing, misappropriating or otherwise violating the intellectual property of others. Additionally, recent reforms and changes at government agencies of the U.S. and those of non-U.S. jurisdictions could increase the uncertainties, timing and costs surrounding the prosecution or maintenance of our patent applications, and the maintenance, enforcement, or defense of our issued patents. We rely on patent, copyright, trade secret and trademark laws in the U.S. and certain other countries to protect our technology, and we generally seek to protect our position by filing patent applications in the U.S. and abroad and by acquiring or in-licensing relevant issued patents or pending applications from third parties. However, these efforts may provide only limited protection. There can be no assurance that we or our licensors will obtain any additional issued patents or that any issued patents we or our licensors obtain will provide us with any competitive advantage.

Pending patent applications cannot be enforced until issued, and then only to the extent the issued claims cover the product candidate or relevant technology. There can be no assurance that our patent applications or the patent applications of our licensors will result in additional patents being issued or that any such issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable, or they may be modified, narrowed in scope, or revoked in proceedings instituted by third parties before various patent offices or in courts in the U.S. and abroad. The degree of future protection for our and our licensor's intellectual property and proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations. Any failure to obtain or maintain patent protection with respect to our technology and product candidates would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

- 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, the non-compliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, narrowed in scope or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates and limiting the scope of our protection in countries outside the United States.

The patent prosecution process is also expensive and time-consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous.

We may be unable to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Furthermore, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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 biotechnology companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our licensors may not result in patents being issued which protect our product candidates and platforms or which effectively prevent others from commercializing competitive product candidates and technologies or otherwise provide any commercial advantage.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Our competitors or other third parties may avail themselves of safe harbor under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) to conduct research and clinical trials and may be able to circumvent our patent rights by developing similar or alternative technologies or products in a non-infringing manner. Any patents that we may own or in-license may be challenged or circumvented by third parties or may be narrowed, rendered unenforceable, or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents.

While we believe our intellectual property allows us to pursue our current development programs, we may not be aware of all third-party intellectual property rights potentially relating to our technology and product candidates. We cannot be certain that we were the first to make the inventions claimed in any owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Publications of discoveries in the scientific literature often lag the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and the inventorship, scope, validity or enforceability of our patents, potential future patents or the patents of our licensors may be challenged in the courts or patent offices in the U.S. and abroad. For example, we may be subject to a third-party pre-issuance submission of prior art, post-grant review or inter partes review at the USPTO, or other similar proceedings including, opposition, derivation, revocation or reexamination proceedings in the U.S. or abroad. A third party may also claim that our patents or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patents, potential future patents or licensed patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us. Such proceedings also may result in substantial cost and require significant time from our scientists, manufacturing staff and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents, potential future patents and patent applications or the patents and patent applications of our licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize our product candidates.

Our commercial success depends significantly on our ability to operate without infringing, misappropriating or otherwise violating the patents and other intellectual property and proprietary rights of third parties.

Our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights of others. Additionally, other entities may have, develop or obtain patents that could impair our competitive position or limit our ability to make, use, sell, offer for sale or import our product candidates. There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology industry. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. Third-party patents or patent applications may include claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Given the vast number of patents in our field of technology, we cannot be certain or guarantee that we do not infringe existing patents or that we will not infringe patents that may be granted in the future.

For example, we are aware of third-party patent rights that could be construed to cover the use of our TN-201 product candidate. We believe that if these third-party patent rights were to be asserted against us, we would have valid defenses against such assertions, including that such patent rights are invalid and/or not infringed. However, if such third-party patent rights were asserted against us and found to be valid, enforceable and infringed, we could be liable for damages and be required to obtain a license to such patent rights prior to commercializing TN-201 both within and outside the U.S., and such license may not be available on commercially reasonable terms or at all. Additionally, we are aware of third-party patent rights related to the use of certain AAV vectors, which have been asserted against others, including in at least one instance against a company for pre-approval activities. If these patent rights were to be asserted against us, we believe we would have valid defenses against such assertions, including that such patent rights are invalid and/or not infringed. However, such defenses may not be successful and we could be liable for damages and need to secure a license to such patent rights, which may not be available on commercially reasonable terms or at all. In the event any of the foregoing were to occur, we may be prevented from further developing and commercializing any affected product candidates, including TN-201.

As the biotechnology industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement, misappropriation or other violation of the patent or other intellectual property rights of third parties.

Although no third party has asserted a claim of patent infringement against us as of the date of this periodic report, there can be no assurance that we will not be subject to claims of patent or other intellectual property infringement in the future. Furthermore, we may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. We may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technology and product candidates. Because patent applications are maintained as confidential for a certain period of time, 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. 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. Identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and ambiguity in the meaning of patent claims. Generative artificial intelligence resources that are publicly available also present a risk that a company may inadvertently obtain, incorporate or use a third party's intellectual property.

Third parties may assert patent infringement claims against us directed at any of our product candidates based on existing patent applications or patents that may be granted in the future, regardless of their merit. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our products, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates. Defense of these claims would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. Because of the inevitable uncertainty in intellectual property litigation, we could lose a patent infringement or other action asserted against us regardless of our perception of the merits of the case. An adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. There is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any future products we may develop and any other future products or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent or find that our technology did not infringe any such claims. Further, even if we were successful in defending against any such claims, such claims could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

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

In addition, our agreements with some of our suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required

or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results or financial condition.

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

Many pharmaceutical companies, biotechnology companies, and academic institutions may have patents and patent applications potentially relevant to our business. We may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders, for example, in order to avoid infringing these third-party patents. We may also require licenses from third parties for certain technologies for use with our product candidates. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies 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 expect that competition for the in-licensing or acquisition of third-party intellectual property rights that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Changes in either the patent laws or in the interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents.

In addition, the U.S. Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents.

Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how patent laws in the U.S. are interpreted. 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. For example, the U.S. Supreme Court held in Amgen v. Sanofi (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. In addition, the U.S. Court of Appeals for the Federal Circuit recently issued a decision involving the interaction of a patent term adjustment, terminal disclaimers, and obvious-type double patenting. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Similarly, foreign courts have made and will continue to make changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. For example, the IRA passed by Congress authorizes the Secretary of the Department of HHS to negotiate prices directly with participating manufacturers for selected medicines covered by Medicare even if these medicines are protected by an existing patent. While we do not believe that the IRA or its effects will impact our ability to obtain patents in the near future, we cannot be certain whether it will affect our patent strategy in the long run. The laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future.

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

We or our licensors may be subject to claims that former employees or other third parties have an ownership interest in our owned patents, patent applications or in-licensed patents, trade secrets or other intellectual property rights as an inventor or co-inventor. For example, although we are not aware of any inventorship disputes as of the date of this periodic report, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or other third parties who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our patents, patent applications or our licensors' owned or in-licensed patents, trade secrets or other intellectual property rights. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property rights that are important to our product candidates. It may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. 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 distraction to management and other employees, and any litigation or the threat of litigation may adversely impact our reputation or affect our ability to hire employees or contract with independent contractors.

In addition, while it is our policy to require our employees, consultants, advisors, contractors and other third parties who may be involved in the conception or development of intellectual property rights to execute agreements assigning such intellectual property rights to us, we or our licensors may be unsuccessful in executing such agreements with each party who, in fact, conceives or develops intellectual property rights that we regard as our own. The assignment of intellectual property rights may not be self-executing or sufficient in scope, or the assignment agreements may be breached, and we or our licensors may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property rights. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us or our licensors may be ineffective in perfecting ownership of inventions developed by that individual. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents or those of our licensors may be eligible for limited patent term restoration under the Hatch-Waxman Amendments. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates.

We may not be granted any extensions for which we apply in the U.S. or any other jurisdiction because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we project or request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we are unable to obtain patent term extension or restoration, or the foreign equivalent, or if the term of any such extension is less than we

project or request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

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

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S., even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the U.S., even in jurisdictions where we or our licensors do pursue patent protection. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own competing products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S.

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

European patent applications now have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unified Patent Court (UPC). This is a significant change in European patent practice. As the UPC is a relatively new court system, there is limited precedent for the court, increasing the uncertainty of any litigation. As a single court system can invalidate a European patent, we, where applicable, have opted out of the UPC and as such, but for proceedings such as an opposition, each European patent would need to be challenged in each individual country.

Geo-political actions in the U.S. and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. Government actions may also prevent filing, prosecution and maintenance of issued patents in various jurisdictions. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in such jurisdictions. If such an event were to occur, it could have a material adverse effect on our business. In addition, jurisdictions outside of the U.S. could also permit our patents to be exploited without consent or compensation. In such circumstances we would not be able to prevent third parties from practicing our inventions or from selling or importing products made using our inventions in and into such jurisdictions. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to the USPTO and various foreign patent offices outside of the U.S. at various points over the lifetime of our current, potential future patents and patent applications and those of our licensors. We rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. An inadvertent lapse or non-compliance with such requirements can sometimes be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business, financial condition and results of operations.

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.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products, but we do not yet own a U.S. registered trademark for our corporate name, "Tenaya". Once filed and registered, our potential future trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these potential future trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. As a means to enforce our potential future trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings, which can be expensive and time-consuming. 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 potential future registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

Additionally, our potential future registered trademarks may not be maintained or enforced. 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 potential future trademark applications and registrations, and our potential future trademarks may not survive such proceedings. If we do not secure registrations for our potential future trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. Our efforts to enforce or protect our proprietary rights related to trademarks, domain names or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

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

In addition to seeking patent protection on the intellectual property underlying our technology and product candidates, we also rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties who have access to such information, and confidential information and invention assignment agreements with employees, consultants, advisors and other third parties involved in the development of intellectual property, we cannot guarantee that we and our licensors have entered into such agreements with each party that may have had access to our trade secrets or proprietary information or that has been involved in the development of intellectual property. Additionally, we cannot provide any assurances that all such agreements have been duly executed, that these parties will not breach such agreements and disclose our proprietary information, including our trade secrets, or that we would be able to obtain adequate remedies for such breaches should they occur. We may not be able to prevent the unauthorized disclosure or use of our trade secrets. 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. 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 U.S. are less willing or unwilling to protect trade secrets. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, our competitors' discovery of our proprietary technology, trade secrets or confidential information or other unauthorized use or disclosure of such information would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, third parties may still derive similar information independently, and we would have no right to prevent them from using that information to compete with us. We expect know-how and information to be disseminated over time within the industry through independent development, publication of journal articles, and movement of personnel between companies and from academic to industry scientific positions. We seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and

physical and electronic security of our information technology systems, but such security measures may be breached, and we may not have adequate remedies for any such breach. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed.

We may be subject to claims that we or our employees, consultants, advisors or contractors have wrongfully used or disclosed alleged confidential information or trade secrets.

As is common in the biotechnology and pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology and pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or consultants inadvertently or otherwise used or disclosed trade secrets or confidential or other information proprietary of their former employers or their former or current clients.

In addition, we have entered into and may in the future enter into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as collaborators, CROs, third-party manufacturers, consultants, potential partners and other third parties. We may become subject to litigation where a third party asserts that we or our employees or other third parties inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of any such claims, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of resources from our business. We cannot predict whether we would prevail in any such claims. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our development and commercialization efforts, including the loss of valuable intellectual property rights or personnel, all of which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Our rights to develop and commercialize our technology and product candidates may be subject, in part, to us obtaining licenses from others and the terms and conditions of such licenses. If we fail to comply with our obligations in any agreement under which we license intellectual property rights from third parties, we could lose licensed rights that are important to our business.

We have entered into and may in the future enter into additional license agreements with third parties to advance our research or allow commercialization of product candidates. These licenses may not provide us with exclusive rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license. If our licensors fail to prosecute, maintain, enforce, and defend, or lose rights to such patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any product that is the subject of such licensed rights could be adversely affected. Even where we have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions taken by or on behalf of our licensors prior to the date upon which we assumed control over patent prosecution.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, our rights to use the licensed intellectual property would not be exclusive and they may be able to license such patents to our competitors, permitting our competitors to market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

For example, the intellectual property we licensed from the University of Texas, Southwestern (UTSW) is subject to certain non-commercial rights reserved by UTSW. Patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in

administrative proceedings brought by or against our licensors or another licensee in response to such litigation or for other reasons. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products, including in territories covered by our licenses.

It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Our current licenses impose, and our future licenses likely will impose, various diligence, royalty payment, milestone payment, insurance and other obligations on us. If we fail to comply with any of these or other obligations in our license agreements, we may be required to pay damages and the licensor may have the right to terminate the licenses. Termination by the licensor would cause us to lose valuable rights and could prevent us from developing and commercializing our product candidates and proprietary technologies. Our business would be seriously harmed if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. If any such event occurs, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical to ours. Further, we may have to negotiate new or reinstated licenses with less favorable terms or we may not have sufficient intellectual property rights to operate our business. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

The agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. Disputes may arise between us and our current and future licensors. In spite of our efforts, our current and future licensors might conclude that we have materially breached our obligations under our license agreements and might therefore terminate such license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property rights, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Our licensors may also own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating our licensor's rights. In addition, while we cannot currently determine the amount of royalty obligations we would be required to pay on the sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in product candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize any product candidates, we may be unable to achieve or maintain profitability.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our preclinical studies and our clinical trials, and plan to rely on third parties to conduct such future drug development activities. These third parties may not perform satisfactorily, including failing to meet completion deadlines, or to comply with applicable regulatory requirements, which may harm our business.

The third parties upon which we rely to conduct our preclinical studies and clinical trials have a significant role in the conduct of such drug development activities and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the amount or timing of resources that any such third party devotes to our

preclinical studies or our clinical trials. The third parties we rely on for these services may also have 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, which could affect their performance on our behalf. Some of these third parties may terminate their engagements with us at any time. We also expect to have to negotiate budgets and contracts with CROs and clinical trial sites and we may not be able to do so on favorable terms. If we need to enter into alternative arrangements with, or replace or add any third parties, it would involve a transition period, and may require substantial cost and extensive management time and focus. Any of these events may delay our drug development activities, increase costs, and materially impact our ability to meet our desired clinical development timelines.

Our heavy reliance on these third parties for such drug development activities reduces our control over these activities. As a result, we have less direct control over the conduct, timing and completion of preclinical studies and clinical trials and the management of data developed through such drug development activities than if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, such as GCP and cGMP, and our reliance on third parties does not relieve us of these responsibilities. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable requirements, such as GCP or cGMP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with applicable regulations. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

We rely on third parties to produce and maintain certain of our product candidates. This increases the risk that we will not have sufficient quality and quantities of product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our business.

We do not have long-term supply agreements, and we purchase our required drug product on a purchase order basis, which means that aside from any binding purchase orders we may have, our supplier could cease supplying to us or change the terms on which it is willing to continue supplying to us at any time. If we experience an unexpected loss of supply of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing preclinical studies or clinical trials. Furthermore, any decision by us to change a third-party manufacturer could result in delays in our manufacturing supply chain which could delay or otherwise impact development of our programs and result in increased costs.

We may be unable to maintain or establish required agreements with third-party manufacturers on acceptable terms. Even if we are able to do so, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule and specifications, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to manufacture our product candidates according to our specifications or comply with applicable regulatory requirements, including cGMP;

- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the infringement, misappropriation or other violation of our intellectual property or proprietary information.

We do not have complete control over all aspects of the manufacturing process of our CDMOs and are dependent on these CDMOs for compliance with cGMP regulations for manufacturing API, drug substance and finished drug products. We are in the process of developing our supply chain for certain of our product candidates and intend to put in place framework agreements under which CDMOs will provide us with necessary quantities of API, drug substance and drug product based on our development needs. As we advance our product candidates through development, we will consider our lack of redundant supply for each of our product candidates to protect against any potential supply disruptions. However, we may be unsuccessful in putting in place such framework agreements or protecting against potential supply disruptions.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

We rely on third-party suppliers for the raw materials required for the production of our product candidates for all of our programs. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our competitors who are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would seriously harm our business.

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

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

From time to time, we evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- 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 programs and initiatives in pursuing such a strategic partnership or acquisition;
- unauthorized use or disclosure of our confidential information accessed in connection with partnership activities;
- the loss of key personnel and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals;
- 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; and
- our inability to realize anticipated efficiencies and strategic benefits from such acquisitions or strategic partnerships.

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

We may enter into collaborations with third parties for the development and commercialization of product candidates. If we are not able to establish those collaborations on commercially reasonable terms or those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We strategically evaluate collaborations and partnerships with biopharmaceutical companies that may have more robust and complementary capabilities and resources to accelerate the development and maximize the availability and potential of our product candidates. The collaboration negotiation process is time-consuming, costly and complex. If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors regarding our business, the applicable product candidate or technology subject to the collaboration negotiation and the related market potential.

If we are unable to reach a definitive agreement, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs or technical capabilities, 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 reduce our planned capital expenditures across other areas of our business or obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

If we enter into any collaboration 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. For example, under our collaboration agreement with Alnylam, following the completion of the validation activities, Alnylam will have complete control of all development, manufacture, regulatory and commercialization activities for any products directed to a collaboration target. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates or technical capabilities would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to, and the manner in which they perform their obligations under, these collaborations and may not perform their obligations as expected;
- the relationship may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business combination or sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial 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;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- we may grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly obtain, maintain, defend, protect or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property-related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all;
- collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our product candidates;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

If an agreement with a collaborator terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Any collaborator may also be subject to many of the risks relating to product development, regulatory approval, and commercialization described in this "Risk Factors" section, and any negative impact on our collaborators may adversely affect us.

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

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties.

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

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

Risks Related to the Securities Market and Ownership of Our Common Stock

The price of our stock is volatile, and you could lose all or part of your investment.

The trading price of our common stock is highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this periodic report, these factors include:

- the timing of achievement of our research, clinical, regulatory and other milestones for our product candidates;
- the results of preclinical studies and clinical trials of our product candidates, those conducted by third parties or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our product candidates or those of our competitors;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the U.S. and other countries;
- application of new standards and practices applied by the FDA for review of product candidates;
- litigation, including developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, licensing arrangements or capital commitments;
- the decision to terminate or dispose of any preclinical or clinical programs;
- the level of research and development expenses incurred for our product candidates and programs;
- actual or anticipated changes in estimates as to financial results, development timelines or coverage and/or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;

- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;
- the impact of any natural disasters or public health emergencies;
- fluctuations in interest rates and inflation rates; and
- general economic, political, industry and market conditions.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

If we do not regain compliance with or continue to satisfy the Nasdaq continued listing requirements, our common stock could be delisted from Nasdaq. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.

The continued listing standards of the Nasdaq Global Select Market require, among other things, that the minimum price of a listed company's stock be at or above $1.00. On January 28, 2026, we received a letter from the Staff of Nasdaq indicating that, based upon the closing bid price of shares of our common stock for the 30 consecutive business day period between December 12, 2025, through January 27, 2026, the Company did not meet the minimum bid price of $1.00 per share required for continued listing on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1). In accordance with Nasdaq's listing rules, we have been afforded 180 calendar days to regain compliance with the bid price requirement. In order to regain compliance, the bid price of our common stock must close at a price of at least $1.00 per share for a minimum of 10 consecutive trading days within the 180-day grace period. In the event we do not regain compliance by the end of the Compliance Period, we may be eligible for additional time to regain compliance (the Second Compliance Period) pursuant to Nasdaq Listing Rule 5810(c)(3)(A)(i) by transferring to the Nasdaq Capital Market. To qualify for the Second Compliance Period, we would need to submit a transfer application and pay an application fee. In addition, we would be required to meet the continued listing requirement for the market value of its publicly held shares and all other initial listing standards for Nasdaq, with the exception of the bid price requirement, and will need to provide written notice of its intention to cure the deficiency during the Second Compliance Period, by effecting a reverse stock split, if necessary. There can be no assurance that we will be eligible for the Second Compliance Period, if applicable, or that the Staff would grant our request for continued listing subsequent to any delisting notification and there can be no assurance that we will be able to regain or maintain compliance with the minimum bid price requirement or any other Nasdaq listing standards, if applicable.

If we do not regain compliance with or continue to satisfy the Nasdaq continued listing requirements, our common stock will be subject to delisting. Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

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

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict. The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the

market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially.

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

As of March 31, 2026, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 23% of our common stock. These stockholders, acting together, may be able to control matters requiring stockholder approval. For example, they may be able to control elections of directors, amendments of our organizational documents or approval of any merger or other major corporate transactions. This concentration of ownership may delay, discourage or prevent a change of control, including unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as a stockholder, entrench our management and board of directors or delay or prevent a merger, takeover or other business combination involving us that other stockholders may desire. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders and might affect the prevailing market price for our common stock.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. For example, we filed (i) on March 4, 2025, a prospectus supplement to our shelf registration statement on Form S-3 that became effective on August 10, 2022 that covered the offering, issuance and sale of 75,000,000 shares of our common stock, Series A Warrants to purchase 75,000,000 shares of our common stock, and Series B warrants to purchase 37,500,000 shares of our common stock, (ii) a new shelf registration statement on Form S-3 that became effective on March 31, 2025, which will allow us to undertake various equity and debt offerings up to $300.0 million (the 2025 Shelf Registration), and (iii) on December 12, 2025, a prospectus supplement to our 2025 Shelf Registration that covered the offering, issuance and sale of 50,000,000 shares of our common stock and warrants to purchase 50,000,000 shares of our common stock.

If the warrants are exercised and shares 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.

We will incur costs as a result of operating as a public company, and our management will devote substantial time to related compliance initiatives. Additionally, if we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

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 Protection Act, as well as rules adopted, and to be adopted, by the SEC and the Nasdaq. As a result of our initiatives to comply with such regulatory requirements, we incur significant legal, accounting and other expenses which may increase after we are no longer an "emerging growth company." Moreover, our management and other personnel need to devote a substantial amount of time to these compliance initiatives.

In particular, as a public company we are required to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm, unless we continue to qualify as a "smaller reporting company" at such time. To achieve compliance with Section 404 within the prescribed periods, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially continue to engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the

detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadlines imposed by the Sarbanes-Oxley Act.

Our internal control over financial reporting will not prevent or detect all errors and all fraud or prevent material weaknesses from being identified in such reporting. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

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

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

The market price of our common stock has been and may continue to be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years and we may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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

Our certificate of incorporation and bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause";
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a poison pill);
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend or repeal specified provisions of our certificate of incorporation and bylaws.

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

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

Our bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are the exclusive forums 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 bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our certificate of incorporation or our bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees. In addition, these exclusive-forum provisions may impose additional litigation costs for stockholders who determine to pursue any such lawsuits against us.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

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

(a) Sales of Unregistered Securities

We had no sales of unregistered equity securities during the period covered by this report that were not previously reported in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

(b) Use of Proceeds from Public Offering of Common Stock

None.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Rule 10b5-1 Trading Arrangements

During the quarter ended March 31, 2026, no director or officer, as defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," each as defined in Regulation S-K Item 408.

Item 6. Exhibits

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date
3.1	Composite Amended and Restated Certificate of Incorporation of Tenaya Therapeutics, Inc., as amended	10-Q	001-40656	3.1	8-9-2023
3.2	Amended and Restated Bylaws of Tenaya Therapeutics, Inc.	8-K	001-40656	3.1	3-21-2023
10.1	2024 Inducement Equity Incentive Plan, as amended and forms of agreements thereunder	8-K	001-40656	10.1	1-30-2026
10.2*#	Collaboration Agreement by and between Alnylam Pharmaceuticals, Inc. and Tenaya Therapeutics, Inc.				
31.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1†	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	Inline XBRL Instance Document–the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.				
104*	Cover page formatted as Inline XBRL and contained in Exhibit 101.				

* Filed herewith.

Portions of this exhibit (indicated by asterisks) have been omitted as the registrant has determined that the omitted information is (1) immaterial and (2) the type the registrant treats as private or confidential.

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

SIGNATURES

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

Tenaya Therapeutics, Inc.

Date: May 6, 2026

By: /s/ Faraz Ali, M.B.A.
Faraz Ali, M.B.A.
Chief Executive Officer and Director
(Principal Executive Officer and Interim Principal Financial Officer)

Exhibit 10.2

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (1) NOT MATERIAL AND (2) THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

COLLABORATION AGREEMENT

by and between

ALNYLAM PHARMACEUTICALS, INC.

and

TENAYA THERAPEUTICS, INC.

COLLABORATION AGREEMENT

THIS COLLABORATION AGREEMENT (this "**Agreement**"), effective as of this 4th day of March, 2026 (the "**Effective Date**"), is entered into by and between Alnylam Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of Delaware having an office at 675 West Kendall Street, Cambridge, MA 02142 ("**Alnylam**"), and Tenaya Therapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware having an office at 171 Oyster Point Blvd, Suite 500, South San Francisco, CA 94080 ("**Tenaya**"). Alnylam and Tenaya are referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, Alnylam has scientific expertise and technology regarding the structure and use of therapeutic products that function through RNA interference;

WHEREAS, Alnylam owns or controls certain fundamental intellectual property relating to RNA interference;

WHEREAS, Tenaya is a biopharmaceutical company focused on the discovery and development of therapies for heart diseases;

WHEREAS, the Parties desire to collaborate to enable Tenaya to use its proprietary technology to identify and validate novel human gene target associations with the treatment, prevention, alteration, or cure of heart and cardiovascular diseases;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:

1. **DEFINITIONS**. Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, and in addition to the terms defined elsewhere in this Agreement, will have the respective meanings set forth below:

1.1 "**Acquirer**" has the meaning set forth in Section 1.20.

1.2 "**Affiliate**" means, with respect to a Person, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such first Person but only for so long as such Person controls, is controlled by or is under common control with such first Person, regardless of whether such Affiliate is or becomes an Affiliate on or after the Effective Date. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity). The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage will be substituted in the preceding sentence; provided that such foreign investor has the power to direct the management or policies of such entity.

1.3 "**Alliance Manager**" has the meaning set forth in Section 5.7.

1.4 "**Alnylam Background Technology**" means (a) Know-How that is necessary or reasonably useful for the performance of the Tenaya Research Activities and (b) Patent Rights that Cover the Know-How described in subsection (a), in each case ((a) and (b)), that are Controlled by Alnylam or its Affiliates as of the Effective Date or during the Term, but excluding the Alnylam Collaboration Technology.

1.5 "**Alnylam Collaboration Know-How**" means (a) any and all Know-How identified, developed, made or discovered solely by or on behalf of either Party or its Affiliates or jointly by or on behalf of the Parties or their respective Affiliates under this Agreement relating to [***], and (b) any other Know-How identified, developed, made or discovered solely by or on behalf of Alnylam or its Affiliates under this Agreement, but in each case ((a) and (b)) excluding Tenaya Platform Know-How.

1.6 "**Alnylam Collaboration Patents**" means any and all Patent Rights that Cover Alnylam Collaboration Know-How.

1.7 "**Alnylam Collaboration Technology**" means the Alnylam Collaboration Know-How and Alnylam Collaboration Patents.

1.8 "**Alnylam Gene Target**" means (a) each Gene Target selected by Alnylam, at Alnylam's discretion, and nominated to the JSC for further validation by the Parties during the Validation Term, excluding any Overlapping Gene Target, or (b) each Overlapping Gene Target deemed an Alnylam Gene Target pursuant to Section 3.2.5; provided that in no event will the Alnylam Gene Targets include [***].

1.9 "**Alnylam Gene Target Information**" has the meaning set forth in Section 8.1.1.

1.10 "**Alnylam Indemnitees**" has the meaning set forth in Section 10.1.

1.11 "**Alnylam Know-How**" means (a) the Alnylam Collaboration Know-How; and (b) the Know-How included in any Alnylam Background Technology.

1.12 "**Alnylam Patents**" means (a) the Alnylam Collaboration Patents; and (b) the Patent Rights included in any Alnylam Background Technology.

1.13 "**Alnylam Tool Compound**" means any research-grade tool Oligonucleotide compound Directed To a Collaboration Target selected by Alnylam for *in vivo* validation under the Research Plan pursuant to Section 3.3.3.

1.14 "**API**" means any active pharmaceutical (including biological) ingredient or component (but excluding, for clarity, an adjuvant or excipient).

1.15 "**Applicable Law**" means applicable laws, rules, and regulations, including any rules, regulations, guidelines, or other requirements of the Regulatory Authorities, that may be in effect from time to time.

1.16 "**Associated**" means that, with respect to a Gene Target, that [***]. "**Association**" shall have a correlative meaning.

1.17"**Breaching Party**" has the meaning set forth in Section 12.2.2.

1.18"**Business Day**" means a day other than a Saturday, Sunday or another day of the week on which commercial banks in San Francisco, California or Boston, Massachusetts, are authorized or required by Applicable Law to remain closed.

1.19"**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term will commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter will end on the last day of the Term.

1.20"**Change of Control**" means, with respect to Tenaya: (a) the acquisition by a Third Party, in one transaction or a series of related transactions, of direct or indirect beneficial ownership of more than fifty percent (50%) of the outstanding voting equity securities of Tenaya; (b) a merger, reorganization or consolidation involving Tenaya as a result of which (i) a Third Party acquires direct or indirect beneficial ownership of more than fifty percent (50%) of the voting power of the surviving entity immediately after such merger, reorganization or consolidation and (ii) the voting securities of Tenaya outstanding immediately prior to such merger, reorganization or consolidation, or any securities into which such voting securities have been converted or exchanged, cease to represent more than fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately following such merger, reorganization or consolidation; or (c) a sale, exclusive license or other transfer of all or substantially all of the assets of Tenaya related to the transactions contemplated by this Agreement in one transaction or a series of related transactions to a Third Party. The acquiring or combining Third Party in any of (a), (b) or (c), and any of such Third Party's Affiliates (whether in existence as of or any time following the applicable transaction, but other than Tenaya and its Affiliates in existence as of the applicable transaction) are referred to collectively herein as the "**Acquirer**."

1.21"**Clinical Trial**" means a human clinical trial of a Licensed Product.

1.22"**Collaboration Target**" means each Tenaya Gene Target, Overlapping Gene Target, Selected Non-Novel Gene Target, or Alnylam Gene Target.

1.23"**Collaboration Target List**" has the meaning set forth in Section 3.2.6.

1.24"**Collaboration Target List Finalization Date**" has the meaning set forth in Section 3.2.6.

1.25"**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of, or sale of a Product, including activities related to marketing, promoting, distributing, and importing such Product, and interacting with Regulatory Authorities regarding any of the foregoing after such Product has received Regulatory Approval, including seeking Pricing and Reimbursement Approvals, maintaining Regulatory Approvals, commercial pharmacovigilance and health outcomes research and publishing scientific studies other than in connection with Development. When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization.

1.26"**Confidential Information**" has the meaning set forth in Section 8.1.1.

1.27"**Confidentiality Agreement**" means that certain Confidentiality Agreement entered into between the Parties dated [***].

1.28"**Control**" means, with respect to a Party and any item of Know-How, Patent Right, or other intellectual property right, the possession by such Party or any of its Affiliates of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of the license and other grants in Section 6.1 or Section 6.2), to grant a license, sublicense or other right to or under such Know-How, Patent Right, or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party. Notwithstanding the foregoing, following a Change of Control of Tenaya, any Know-How, Patent Right, or other intellectual property right owned or controlled by the Acquirer shall not be deemed "Controlled" by Tenaya or its Affiliates for the purpose of this Agreement, except to the extent such Know-How, Patent Right, or other intellectual property right is actually used by Tenaya or its Affiliates, or the Acquirer, in the performance of Tenaya's obligations under this Agreement following the consummation of such Change of Control.

1.29"**Cover**," "**Covering**" or "**Covers**" means, as to a product, any Patent Rights, that, in the absence of a license granted under, or ownership of, such Patent Rights, the manufacture, use, offer for sale, sale, importation or other Exploitation of such product would infringe such Patent Rights or, as to a pending claim included in such Patent Rights, the manufacture, use, offer for sale, sale, importation or other Exploitation of such product would infringe such Patent Rights if such pending claim were to issue in an issued patent.

1.30"**Data Package**" means, individually and collectively, any *In Vitro* Data Package, *In Vivo* Data Package or Tenaya Nominated Gene Target Data Package.

1.31"**Deadlocked Gene Target**" has the meaning set forth in Section 3.2.2.

1.32"**Development**" means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation (but excluding such scale-up, qualification and validation with respect to establishing, or otherwise causing to become operational, any manufacturing facilities), quality assurance/quality control, Clinical Trials, including manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of drug approval applications, regulatory affairs with respect to the foregoing, medical affairs, medical information, medical education, health economic and outcomes research, market research, and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining a Regulatory Approval. Development also includes the foregoing activities, if any, with respect to any devices (including diagnostics) designed for use with a Product. When used as a` verb, "Develop" means to engage in Development.

1.33"**Development and Regulatory Milestone**" has the meaning set forth in Section 7.2.1.

1.34"**Directed To**" means, with respect to a product and a Gene Target, that such product is designed to directly interact with, or modulate the expression of such Gene Target or the protein it encodes and such interaction or modulation causes the product's primary diagnostic, prophylactic or therapeutic effect.

1.35"**Disclosing Party**" has the meaning set forth in Section 8.1.1.

1.36"**Dispute**" has the meaning set forth in Section 13.12.

1.37"**Dollars**" or "**$**" means United States Dollars.

1.38"**Effective Date**" has the meaning set forth in the preamble.

1.39"**Evaluation Term**" means, with respect to a given Non-Alnylam Collaboration Target, the period commencing upon the expiration of the Validation Term and ending on the earlier of (a) Alnylam's commencement of an NHP PD Study with a Licensed Product Directed To such Non-Alnylam Collaboration Target or (b) twenty four (24) months following the expiration of the Validation Term.

1.40"**Executive Officer**" means, for Alnylam, its [***], and for Tenaya, its [***]. Either Party may change its Executive Officer upon written notice to the other Party; provided that such replacement individual has decision-making authority on behalf of such Party in respect of this Agreement.

1.41"**Exploit**" means, with respect to a product, to make, have made, import, use, sell, or offer for sale, including to research (including pre-clinical and clinical research), Develop, Commercialize, register, manufacture, have manufactured, hold, or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market, or have sold or otherwise dispose of such product. When used as a noun, "**Exploitation**" means the act of Exploiting a product.

1.42"**FDA**" means the United States Food and Drug Administration and any successor Governmental Authority in the United States having substantially the same function.

1.43"**Field**" means the diagnosis, prevention, treatment, control, prophylaxis or palliation of any disease, disorder or condition in humans in any tissue or organ.

1.44"**First Commercial Sale**" means, with respect to a given Licensed Product in a given country, the first commercial transfer or disposition for value of such Licensed Product for end use in such country to a Third Party (not being a Sublicensee for the relevant Licensed Product) by Alnylam or any of its Affiliates or Sublicensees after such Licensed Product has been granted Regulatory Approval and, where applicable, necessary Pricing and Reimbursement Approval, in each case, in such country and where the sale results in a recordable Net Sale. The following sales will not constitute a "First Commercial Sale": (a) any distribution or other sale solely for so-called investigational new drug sales, clinical studies, compassionate or emergency use, named patient programs, promotional samples, testing samples, donations, or any similar instances, in each case at or below cost; and (b) sales between Alnylam and its Affiliates or Sublicensees if such sales are not intended for end use.

1.45"**FTE**" means a qualified full time person, or more than one person working the equivalent of a full-time person, where "full time" is equal to a person working a total of [***] working hours in a Calendar Year on scientific or technical work, in each case, as carried out by a qualified employee of Tenaya or Alnylam, as applicable. Overtime, and work on weekends, holidays, and the like will not be counted with any multiplier (e.g., time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. For clarity, any general corporate personnel (including support functions such as finance, legal, or business development) will not constitute an FTE.

1.46"**FTE Costs**" means, for any period, the FTE Rate multiplied by the number of any applicable FTEs in such period.

1.47"**FTE Rate**" means the rate that covers all costs and expenses of the applicable FTE including salary, benefits, bonuses, other compensation costs and expenses and all indirect costs and expenses including administration, facility costs and overhead, which [***].

1.48"**GAAP**" means United States generally accepted accounting principles that are currently used at the relevant time and consistently applied by the applicable Party.

1.49"**Gene Target**" means any human gene.

1.50"**Governmental Authority**" means any applicable government authority, court, tribunal, arbitrator, agency, legislative body, commission or other instrumentality of (a) any government of any country or territory, (b) any state, province, county, city or other political subdivision thereof, or (c) any supranational body.

1.51"***In Vitro* Data Package**" has the meaning set forth in Section 3.3.2.

1.52"***In Vitro* Validation Activities**" has the meaning set forth in Section 3.3.1.

1.53"***In Vivo* Data Package**" has the meaning set forth in Section 3.3.4.

1.54"***In Vivo* Validation Activities**" has the meaning set forth in Section 3.3.3.

1.55"**IND**" means (a) an investigational new drug application filed with the FDA for authorization to commence Clinical Trials and its equivalent in other countries or regulatory jurisdictions, and (b) all supplements and amendments that may be filed with respect to the foregoing.

1.56"**Initial JSC Meeting**" has the meaning set forth in Section 3.2.1.

1.57"**Initiation**" means, with respect to a Clinical Trial, the first dosing of the first human subject in such Clinical Trial.

1.58"**Joint Collaboration Technology**" means any and all (a) Know-How, other than Alnylam Collaboration Know-How or Tenaya Platform Improvements, that is identified, developed, made or discovered jointly by or on behalf of the Parties or their respective Affiliates under this Agreement, and (b) Patent Rights that Cover the Know-How described in subsection (a).

1.59"**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 5.1.

1.60"**Know-How**" means all (a) technical, scientific, and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results, and Materials, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols; assays; and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed, and (b) any physical embodiments of any of the foregoing, but in each case ((a) and (b)), excluding any Patent Rights.

1.61"**Licensed Product**" means any therapeutic product that is Directed To a Non-Alnylam Collaboration Target, alone or in combination with one or more other APIs, in any and all forms, presentations, delivery systems, dosages and formulations.

1.62"**Licensed Technology**" means, collectively, the Tenaya Collaboration Technology and Tenaya's interest in the Joint Collaboration Technology.

1.63"**Losses**" has the meaning set forth in Section 10.1.

1.64"**Major European Country**" means the United Kingdom, France, Germany, Italy or Spain.

1.65"**Materials**" means all tangible compositions of matter, devices, articles of manufacture, assays, animal models, biological, chemical, or physical materials, and other similar materials, including cell lines and animal models; provided that Materials excludes Products.

1.66"**Net Sales**" means, with respect to a Licensed Product, the gross amount invoiced by or on behalf of Alnylam or its Affiliates or Sublicensees (each of the foregoing Persons, a "**Selling Party**") for the sale or other disposition of such Licensed Product to a Third Party (including Third Party distributors), in bona fide arms' length transactions in the Territory, less the following deductions (from the gross amount invoiced), in each case, pertaining to such Licensed Product and actually allowed and taken by such Third Party and not otherwise recovered by or reimbursed to the Selling Party:

(a) [***].

Such amounts will be determined consistent with a Selling Party's customary practices and in accordance with GAAP. It is understood that any accruals for individual items reflected in Net Sales are periodically (at least Calendar Quarterly) trued up and adjusted by each Selling Party consistent with its customary practices and in accordance with GAAP. In no event shall any particular amount identified above be deducted more than once in calculating Net Sales (*i.e.*, no "double counting" of deductions).

Notwithstanding any provision to the contrary set forth in this Agreement, Net Sales will not include any distribution or other sale of Licensed Product solely for so-called investigational new drug sales, clinical studies, compassionate or emergency use, named patient or single patient programs, expanded access or indigent programs, promotional samples, testing samples, donations, or any other similar instances, in each case at or below cost.

Sale or transfer of Licensed Products between any of the Selling Parties will not result in any Net Sales if such sales are not intended for end use, with Net Sales to be based only on any subsequent sales or dispositions to a non-Selling Party. To the extent that any Selling Party receives consideration other than or in addition to cash upon the sale or disposition of a Licensed Product to a non-Selling Party in a given country, Net Sales will be calculated based on the average price charged for such Licensed Product in such country, as applicable, during the applicable period, or in the absence of such sales, based on the fair market value of such Licensed Product, as reasonably determined by the Parties in good faith. For clarity, Net Sales will not include amounts or other consideration received by a Selling Party from a non-Selling Party to the extent paid in consideration of the grant of a sublicense or co-promotion or distribution right to such non-Selling Party.

1.67"**NHP PD Study**" means any pharmacodynamic study of a Licensed Product in non-human primates.

1.68"**Non-Alnylam Collaboration Target**" means each (a) Tenaya Gene Target, (b) Overlapping Gene Target, or (c) Selected Non-Novel Gene Target.

1.69"**Non-Alnylam Collaboration Target Information**" has the meaning set forth in Section 8.1.1.

1.70"**Non-Breaching Party**" has the meaning set forth in Section 12.2.2.

1.71"**Non-Novel Gene Target**" has the meaning set forth in Section 3.2.1.

1.72"**Oligonucleotide**" means any modified or unmodified single- or double-stranded RNA or DNA oligonucleotide that acts on a Gene Target.

1.73"**Out-of-Pocket Costs**" means costs and expenses paid by a Party or any of its Affiliates to Third Parties for goods or services, including [***] but not including any FTE Costs, or such Party's, or any of its Affiliates', other internal or general overhead costs or expenses.

1.74"**Overlapping Gene Target**" has the meaning set forth in Section 3.2.5.

1.75"**Patent Rights**" means (a) all issued patents (including any extensions, restorations by any existing or future extension or registration mechanism (including patent term adjustments, patent term extensions, supplemental protection certificates or the equivalent thereof), substitutions, confirmations, re-registrations, re-examinations, and patents of addition); (b) patent applications (including all provisional applications, substitutions, requests for continuation, continuations, continuations-in-part, divisionals and renewals); (c) inventor's certificates; and (d) all equivalents of the foregoing in any country of the world.

1.76"**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.77"**Phase I Clinical Trial**" means a Clinical Trial of a product that satisfies the requirements of 21 C.F.R. 312.21(a) (or its successor regulation or its equivalent in any other jurisdiction) and is designed to assess the safety of such product in patients.

1.78"**Phase II Clinical Trial**" means a Clinical Trial of a product that satisfies the requirements of 21 C.F.R. § 312.21(b) (or its successor regulation or its equivalent in any other jurisdiction) and is intended to explore one or more doses, dose response, and duration of effect, and to generate initial evidence of clinical activity and safety, in the target patient population.

1.79"**Phase III Clinical Trial**" means a Clinical Trial of a product that satisfies the requirements of 21 C.F.R. § 312.21(c) (or its successor regulation or its equivalent in any other jurisdiction) and is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product.

1.80"**Platform Access Fee**" has the meaning set forth in Section 7.1.

1.81"**Pricing and Reimbursement Approval**" means such approval, agreement, determination or governmental decision establishing prices for a Product that can be charged to consumers and will be reimbursed by Regulatory Authorities in countries where Regulatory Authorities of such countries approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.82"**Primary Cardiovascular Indication**" means each of the following: [***]. With respect to a particular Gene Target, only one of (a) through (f) shall constitute the applicable Primary Cardiovascular Indication; with respect to each Tenaya Nominated Gene Target, Tenaya shall specify the applicable Primary Cardiovascular Indication for such Gene Target in the applicable Tenaya Nominated Gene Target Data Package (for clarity, if Tenaya has Associated such Gene Target with multiple indications, [***]).

1.83"**Product**" means any product that is Directed To a Collaboration Target, alone or in combination with one or more other APIs, in any and all forms, presentations, delivery systems, dosages and formulations.

1.84"**Public Knowledge**" means information becomes publicly known or available through no fault of, or breach of the confidentiality obligations of this Agreement by, Alnylam; provided that information shall not be considered Public Knowledge if such information becomes publicly known or available as a result of (a) the publication of Patent Rights filed by Alnylam, by Tenaya after the Effective Date with Alnylam's prior written consent, or by Tenaya as of the Effective Date, or (b) its disclosure, publication or presentation by Alnylam, by Tenaya after the Effective Date with Alnylam's prior written consent, or by Tenaya as of the Effective Date.

1.85"**Quarterly Research Expense Report**" has the meaning set forth in Section 2.4.2.

1.86"**Receiving Party**" has the meaning set forth in Section 8.1.1.

1.87"**Regulatory Approval**" means, with respect to a country in the Territory, any and all approvals (including drug approval applications), licenses, registrations, or authorizations of any Regulatory Authority necessary to commercially distribute, sell, or market a Product in such country, including, where applicable, (a) Pricing and Reimbursement Approval in such country, (b) pre- and post-approval marketing authorizations (including any prerequisite manufacturing approval or authorization related thereto), and (c) labeling approval.

1.88"**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils, or other government entities regulating or otherwise exercising authority with respect to the Exploitation of a Product in the Territory.

1.89"**Regulatory Materials**" means all (a) applications (including all INDs and drug approval applications and other major regulatory filings), registrations, licenses, authorizations, and approvals (including Regulatory Approvals) and (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files.

1.90"**Reimbursement Cap**" has the meaning set forth in Section 2.3.

1.91"**Replacement Gene Target**" has the meaning set forth in Section 3.2.3.

1.92"**Research Budget**" has the meaning set forth in Section 2.2.

1.93"**Research Data**" has the meaning set forth in Section 2.9.

1.94"**Research Plan**" has the meaning set forth in Section 2.1.

1.95"**Sales Milestone**" has the meaning set forth in Section 7.3.1.

1.96"**Selected Non-Novel Gene Target**" has the meaning set forth in Section 3.2.2.

1.97"**Selling Party**" has the meaning set forth in Section 1.66.

1.98"**Sublicensee**" means a Third Party that is granted, in accordance with this Agreement, a (sub)license by Alnylam or its Affiliates to intellectual property licensed under this Agreement by Alnylam or its Affiliates to, or to Alnylam and its Affiliates by, Tenaya or its Affiliates, to Develop or Commercialize a Product.

1.99"**Tenaya Collaboration Know-How**" means all Know-How (a) identified, developed, made or discovered by or on behalf of Tenaya during the Validation Term or described in any Data Package with respect to a Collaboration Target, or (b) any other Know-How Controlled by Tenaya or its Affiliates as of the Effective Date or during the Term of this Agreement related to [***], but in each case ((a) and (b)) excluding Tenaya Platform Know-How.

1.100"**Tenaya Collaboration Patents**" means all Patent Rights that Cover Tenaya Collaboration Know-How.

1.101"**Tenaya Collaboration Technology**" means the Tenaya Collaboration Know-How and Tenaya Collaboration Patents.

1.102"**Tenaya Gene Target**" means each Tenaya Nominated Gene Target that (a) is deemed a Tenaya Novel Gene Target by the JSC pursuant to Section 3.2.1, excluding any Overlapping Gene Target, or (b) is an Overlapping Gene Target deemed a Tenaya Novel Gene Target pursuant to Section 3.2.5.

1.103"**Tenaya Indemnitees**" has the meaning set forth in Section 10.2.

1.104"**Tenaya Nominated Gene Target**" means a Gene Target that, prior to the nomination of such Gene Target by Tenaya pursuant to Section 3.1 meets the following qualifications: [***]. For clarity, the Tenaya Nominated Gene Targets shall include the Gene Targets set forth on **Schedule 1.104**.

1.105"**Tenaya Nominated Gene Target Data Package**" means a distinct data package with data and information supporting the Association of the Tenaya Nominated Gene Target and the applicable Primary Cardiovascular Indication that includes: (a) with respect to each Tenaya Nominated Gene Target, all available information related to the key data points in the table set forth in **Schedule 1.104**, including [***]; (b) any other Know-How Controlled by Tenaya reasonably necessary or useful for Alnylam to determine whether to proceed to *in vivo* activities with respect to such Gene Target under the Research Plan; and (c) any unpublished provisional or other Patent Right that Covers the Tenaya Nominated Gene Target.

1.106"**Tenaya Novel Gene Target**" means a Tenaya Nominated Gene Target where the identity of such Tenaya Nominated Gene Target and association of such Tenaya Nominated Gene Target with the

incidence, treatment, palliation, cure, prevention, or diagnosis of the applicable Primary Cardiovascular Indication[***].

1.107"**Tenaya Patents**" means (a) the Tenaya Collaboration Patents, and (b) the Tenaya Platform Patents.

1.108"**Tenaya Platform Improvements**" means all Know-How developed or discovered solely by or on behalf of either Party or its Affiliates or jointly by or on behalf of the Parties or their respective Affiliates under this Agreement through or as a result of the Research Plan, that is necessary in the practice of, or is otherwise directed to, the Tenaya Platform Know-How (other than Third Party Models), including any and all improvements, enhancements, modifications, substitutions, alternatives or alterations to Tenaya Platform Know-How (other than Third Party Models).

1.109"**Tenaya Platform Know-How**" means, at any given time during the Term, [***]. Tenaya Platform Know-How includes Tenaya Platform Improvements, but shall not include [***].

1.110"**Tenaya Platform Patents**" means all Patents Rights that Cover Tenaya Platform Know-How, including Tenaya Platform Improvements. For clarity, Tenaya Platform Patents exclude Tenaya Collaboration Patents.

1.111"**Tenaya Platform Technology**" means the Tenaya Platform Know-How and Tenaya Platform Patents.

1.112"**Tenaya Research Activities**" has the meaning set forth in Section 2.6.

1.113"**Tenaya Research Expenses**" has the meaning set forth in Section 2.3.

1.114"**Tenaya Technology**" means, collectively, Tenaya Platform Technology and Tenaya Collaboration Technology.

1.115"**Term**" has the meaning set forth in Section 12.1.

1.116"**Terminated Collaboration Target**" means any Non-Alnylam Collaboration Target with respect to which this Agreement has been terminated in accordance with any of the provisions of Sections 3.3.5, 3.4, or 12.2. For clarity, if this Agreement is terminated in its entirety, all Non-Alnylam Collaboration Targets will be Terminated Collaboration Targets.

1.117"**Territory**" means all countries of the world.

1.118"**Third Party**" means any Person other than the Parties and their respective Affiliates.

1.119"**Third Party Model**" means any *in vitro* or *in vivo* model that is not in Tenaya's possession on the Effective Date and is obtained by Tenaya during the Validation Term solely for use in Tenaya Research Activities at Alnylam's request.

1.120"**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

1.121"**United States**" means the United States of America and its territories, possessions and commonwealths.

1.122"**Validation Term**" means the period commencing on the Collaboration Target List Finalization Date and ending on the date that is twenty four (24) months following the Collaboration Target List Finalization Date.

2. RESEARCH COLLABORATION.

2.1 **Research Plan**. During the Validation Term, the Parties will perform non-clinical Development activities under this Agreement in accordance with the written plan that sets forth: (a)(i) the *in vitro* validation activities for Collaboration Targets to be performed by or on behalf of Tenaya under such plan during the Validation Term, and (ii) the *in vivo* validation activities for Collaboration Targets to be performed by or on behalf of Tenaya under such plan during the Validation Term, (b) the activities to be performed by or on behalf of Alnylam under such plan during the Validation Term, (c) the Data Packages, Research Data and other deliverables to be provided by Tenaya to Alnylam, (d) any Subcontractors to be engaged by Tenaya to perform the activities described in the foregoing clause (a), (e) the Research Budget as further described in Section 2.2, (f) a timeline for completion of the applicable Tenaya Research Activities, and (g) the resources to be provided by Tenaya in furtherance of performing the applicable Tenaya Research Activities (such plan, as may be amended in accordance with this Agreement, the "**Research Plan**"). The initial Research Plan agreed to by the Parties is attached hereto and incorporated herein as **Exhibit A**. Either Party may propose updates to the Research Plan from time to time and submit the same to the JSC. The JSC will review, discuss, and determine whether to approve each proposed updated Research Plan, provided that if the JSC cannot reach agreement, [***]. If the JSC approves an update to the Research Plan, then the Research Plan will be deemed amended as of the date of such approval and such amended Research Plan will supersede the prior Research Plan.

2.2 **Research Budget**. The Research Plan will include a written budget pursuant to which Tenaya, its Affiliates, and its Subcontractors will perform the Tenaya Research Activities, which budget will include a good-faith estimate of (a) the number of FTEs to be dedicated by Tenaya to performing such activities under the Research Plan, and (b) any Out-of-Pocket Costs expected to be incurred in the performance of such activities (the "**Research Budget**"). The initial Research Budget agreed to by the Parties is included in **Exhibit A**. Under the Research Budget, all internal personnel and resources of Tenaya under the Research Budget will be expressed in terms of FTEs (with costs budgeted as calculated using the FTE Rate) plus the Out-of-Pocket Costs to be incurred in the performance of the Tenaya Research Activities outlined in the Research Plan. Either Party may propose updates to the Research Budget from time to time (including in connection with update to the Tenaya Research Activities under the Research Plan) and submit the same to the JSC. The JSC will review, discuss, and determine whether to approve each proposed updated Research Budget, provided that if the JSC cannot reach agreement [***]. If the JSC approves an update to the Research Budget, then the Research Budget will be deemed amended as of the date of such approval and such amended Research Budget will supersede the prior Research Budget. Subject to Section 2.3, [***].

2.3 **Research Funding**. During the Validation Term, Alnylam will reimburse Tenaya for all FTE Costs and Out-of-Pocket Costs, in each case, incurred by Tenaya in furtherance of the Tenaya Research Activities to the extent actually incurred in accordance with the applicable Research Plan (the "**Tenaya Research Expenses**") up to, in the aggregate and subject to the remainder of this Section 2.3, [***] (the "**Reimbursement Cap**"). If Tenaya incurs, or is expected to incur, Tenaya Research Expenses in excess of [***] of the Reimbursement Cap for the Validation Term, then the Parties, through the JSC, will discuss

whether to approve an increase in the amount budgeted in the Research Budget. If the JSC does not approve an increase to the applicable Research Budget, then [***].

2.4 **Tenaya Research Expense Reporting**.

2.4.1 No later than [***] prior to the end of each Calendar Quarter during the Validation Term, Tenaya will provide Alnylam with a written report containing (a) actual Tenaya Research Expenses incurred by or on behalf of Tenaya during the first two months of such Calendar Quarter and (b) a good faith estimate (which, for clarity, will not be binding) of Tenaya Research Expenses to be incurred by or on behalf of Tenaya during the third month of such Calendar Quarter; in each case ((a) and (b)), including (i) a breakdown of the number of FTEs and FTE Costs, and the amount of any Out-of-Pocket Costs incurred or expected to be incurred in furtherance of the Tenaya Research Activities in accordance with the Research Budget, and (ii) an accounting of such costs as compared to the amounts set forth in the Research Budget.

2.4.2 Within [***] after the end of each Calendar Quarter during the Validation Term, Tenaya will provide Alnylam with a reasonably detailed statement setting forth (a) actual Tenaya Research Expenses incurred by or on behalf of Tenaya during such Calendar Quarter, and (b) a forecast of the costs and expenses that Tenaya expects to incur in the performance of the Tenaya Research Activities during the upcoming four Calendar Quarters (which, for clarity, will not be binding), which costs and expenses must be in accordance with the Research Plan and Research Budget in accordance with the terms hereof in a format to be agreed upon by the Parties (each such report, a "**Quarterly Research Expense Report**").

2.5 **Payments**. All payments made by Alnylam in respect of the Tenaya Research Expenses will be made in arrears pursuant to invoices submitted by Tenaya to Alnylam simultaneously with delivery of the Quarterly Research Expense Report after the end of the applicable Calendar Quarter in which such Tenaya Research Expenses were incurred. Alnylam will reimburse Tenaya all undisputed amounts of Tenaya Research Expenses set forth in any Quarterly Research Expense Report no later than [***] after Alnylam's receipt thereof, provided, however, that in no event will Alnylam be required to pay any amounts set forth in any Quarterly Research Expense Report in respect of any Tenaya Research Activities that were performed more than [***] prior to Alnylam's receipt of such invoice. Any dispute relating to Tenaya Research Expenses shall be resolved pursuant to Section 7.6.

2.6 **Research Efforts**. Tenaya will be responsible for (i) performing all activities assigned to it under the Research Plan and (ii) preparing and delivering all Data Packages, Research Data and other deliverables that are to be delivered by Tenaya under the terms of the Research Plan (collectively, together with any other activity expressly set forth under this Agreement to be performed by or on behalf of Tenaya, the "**Tenaya Research Activities**"). Tenaya will perform, or have performed, all Tenaya Research Activities in accordance with the Research Plan and otherwise in accordance with this Agreement, and will use reasonable efforts to comply with the timelines set forth in the Research Plan for performance of the applicable activities. Tenaya will perform or cause to be performed any and all of its activities for the Research Plan, including its activities under the Research Plan, in a good scientific manner and in compliance with all Applicable Law. Tenaya will maintain laboratories, offices and all other facilities at its own cost and expense and risk necessary to carry out its responsibilities under the Research Plan.

2.7 **Cooperation**. Until the expiration of the Evaluation Term, promptly after request by Alnylam through the Alliance Managers, Tenaya will (and will cause its Affiliates to) cooperate with Alnylam and provide reasonable assistance to Alnylam to enable Alnylam (and its Affiliates) to conduct its activities

under this Agreement, as reasonably requested by Alnylam, including (a) providing Alnylam (and its designees) with reasonable access by teleconference or in-person (as requested by Alnylam) to then-employed personnel of Tenaya (and personnel of its Affiliates) to answer questions related to its activities pursuant to this Agreement and (b) providing Know-How that is licensed to Alnylam under this Agreement to the extent that it is necessary or reasonably useful for Alnylam to perform its activities under this Agreement, including copies of all material scientific information and data related to each Collaboration Target. Tenaya will provide [***] free of charge for such cooperation and assistance, and Alnylam will reimburse Tenaya for all (i) Out-of-Pocket Costs and (ii) FTE Costs (after such [***]), in each case ((i) and (ii)) associated with such cooperation and assistance.

2.8 **Subcontracting**. Each Party may subcontract any of its activities under this Agreement to a Third Party (each such Third Party, a "**Subcontractor**"), provided that Tenaya shall not subcontract any of its research activities under this Agreement to a Third Party without Alnylam's prior written consent, not to be unreasonably withheld, conditioned or delayed (for clarity, any subcontractors listed in the Research Plan shall be deemed approved by Alnylam); provided further that any subcontract entered into by each Party pursuant to this Section 2.8 must (a) be in writing, (b) be consistent with the terms and conditions of this Agreement, including containing confidentiality provisions at least as protective as those contained in Article 8, and (c) in case of subcontract by Tenaya, provide Alnylam with the same rights with respect to any intellectual property arising from the subcontracted activities as it would have if Tenaya performed such activities under this Agreement. In any event, each Party will (x) oversee the performance by its Subcontractors of the activities subcontracted pursuant to this Section 2.8 in a manner that would be reasonably expected to result in their timely and successful completion and (y) be responsible and liable for the actions and omissions of its Subcontractors as between the Parties. No subcontracting pursuant to this Section 2.8 will relieve any Party of any of its obligations, or deprive the other Party of any of its rights, under this Agreement.

2.9 **Records and Reports**. Each Party will, and will ensure that its Subcontractors, maintain complete, current and accurate records of all of its research activities under this Agreement, and all data and other information resulting from such research activities, which records will (a) be in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, and in compliance with Applicable Law, (b) properly reflect all work done and results achieved in the performance of such research activities, and (c) record only such research activities and will not include or be commingled with records of activities that are not conducted under this Agreement. Each Party will retain, or cause to the retained, such records for at least [***] after the expiration or termination of this Agreement, or for such longer period as may be required by Applicable Law. For each Collaboration Target, Tenaya will provide to the JSC on a [***] basis a summary of material data with respect to any research activities under the Research Plan for such Collaboration Target, including the data regarding its Associated Primary Cardiovascular Indication, and, upon the reasonable request by Alnylam, will provide Alnylam copies of or access to all data and other material Know-How, results, and analyses with respect to such research activities for such Collaboration Target (collectively, "**Research Data**").

3. TARGET SELECTION AND VALIDATION.

3.1 **Target Nomination**. Within [***] following the Effective Date, at an agreed time and in a simultaneous manner (a) Tenaya will nominate at least [***] Tenaya Nominated Gene Targets in writing to the JSC members, and (b) Alnylam will nominate up to [***] Gene Targets in writing to the JSC members. Also, within such [***] period, Tenaya shall provide a complete Tenaya Nominated Gene Target

Data Package generated by Tenaya that supports the Association of each Tenaya Nominated Gene Target and the applicable Primary Cardiovascular Indication.

3.2 **Target Selection**.

3.2.1Within [***] following the Effective Date, the JSC will meet (the "**Initial JSC Meeting**") to (a) review the Tenaya Nominated Gene Targets and Gene Targets nominated by Alnylam, and (b) determine which of the Tenaya Nominated Gene Targets qualify as Tenaya Novel Gene Targets and which of the Tenaya Nominated Gene Targets do not qualify as Tenaya Novel Gene Targets (each such non-qualifying Gene Target, a "**Non-Novel Gene Target**"). For clarity, the determination of whether a Tenaya Nominated Gene Target qualifies as a Tenaya Novel Gene Target shall be solely based on the requirements contained in the definition of "Tenaya Novel Gene Target" [***].

3.2.2With respect to (a) any Tenaya Nominated Gene Target deemed a Non-Novel Gene Target at the Initial JSC Meeting, or (b) each Tenaya Nominated Gene Target which the JSC does not mutually agree is or is not a Tenaya Novel Gene Target (each such target described in the foregoing clause (b), a "**Deadlocked Gene Target**"), Alnylam will determine at the Initial JSC Meeting to either: (a) reject such Non-Novel Gene Target or Deadlocked Gene Target, in which case such rejected Gene Target shall be deemed a "**Rejected Gene Target**"; or (b) select such Non-Novel Gene Target or Deadlocked Gene Target (such selected Non-Novel Gene Target or Deadlocked Gene Target, a "**Selected Non-Novel Gene Target**") to proceed under the Research Plan. For clarity, a Rejected Gene Target shall not be deemed a Collaboration Target, and Alnylam shall not have any rights and Tenaya shall not have any obligations, in each case under this Agreement with respect to any such Rejected Gene Target.

3.2.3With respect to each Rejected Gene Target, Tenaya shall have the right to nominate an additional Gene Target that qualifies as a Tenaya Nominated Gene Target (each, a "**Replacement Gene Target**") at the Initial JSC Meeting; provided, however that Tenaya may not nominate as a Replacement Gene Target any Gene Target previously nominated by Alnylam as an Alnylam Gene Target. Each Replacement Gene Target will be treated as a Tenaya Nominated Gene Target under this Section 3.2; for clarity, Tenaya will provide a Tenaya Nominated Gene Target Data Package for each Replacement Gene Target. Within [***] following the Initial JSC Meeting, the JSC will meet to review the Replacement Gene Targets, if any, and will determine which qualify as Tenaya Novel Gene Targets and which are Non-Novel Gene Targets or Deadlocked Gene Targets (which may be rejected as Rejected Gene Targets or selected by Alnylam as Selected Non-Novel Gene Targets).

3.2.4For each Tenaya Nominated Gene Target (including any Replacement Gene Target) that is determined to be a Rejected Gene Target and for which either (a) Tenaya fails to nominate a Replacement Gene Target under Section 3.2.3, or (b) Tenaya nominates a Replacement Gene Target under Section 3.2.3 but the Replacement Gene Target does not qualify as a Tenaya Novel Gene Target and is not selected by Alnylam as a Selected Non-Novel Gene Target, the payment due to Tenaya pursuant to Section 7.1 will be reduced by $500,000 for each such Rejected Gene Target.

3.2.5To the extent Alnylam and Tenaya each nominate the same Gene Target (regardless if such nominations are for the same Primary Cardiovascular Indication for such Gene Target) at the Initial JSC Meeting and such Gene Target qualifies as a Tenaya Novel Gene Target, each such overlapping Gene Target will be deemed an "**Overlapping Gene Target**," except that, notwithstanding the foregoing, (a) if both Parties nominate [***], then [***] will be deemed a Tenaya Novel Gene Target, and (b) if both Parties nominate [***], then [***] will be deemed an Alnylam Gene Target.

3.2.6Following the review of the Gene Targets nominated by each Party under this Section 3.2 at the Initial JSC Meeting (if there are no Replacement Gene Targets named) or within [***] of the subsequent JSC meeting (if there is one or more Replacement Gene Targets named), the JSC shall agree in writing on a list of Gene Targets to be Collaboration Targets subject to this Agreement (such list, the "**Collaboration Target List**" and the date such list is agreed in writing, the "**Collaboration Target List Finalization Date**"). The Collaboration Target List will identify each Gene Target as one of the following: (a) a Tenaya Gene Target, (b) a Selected Non-Novel Gene Target, (c) an Overlapping Gene Target, or (d) an Alnylam Gene Target. Alnylam may prioritize the order the Alnylam Gene Targets enter *In Vitro* Validation Activities by written notice to Tenaya. The Parties may agree to update the Collaboration Target List from time to time through mutual agreement.

3.3 **Target Validation**. During the Validation Term (which may be extended upon the mutual agreement of the Parties), the Parties will conduct *in vivo* and *in vitro* target validation research and development activities in accordance with the Research Plan and Research Budget; provided however that notwithstanding the expiration of the Validation Term, Tenaya will complete any *in vivo* validation activities in progress at the time of expiration of the Validation Term, at Alnylam's cost and expense, in accordance with the Research Plan and Research Budget and shall remain obligated to deliver to Alnylam the associated *In Vivo* Data Package; provided further that Alnylam shall not modify or amend the Research Plan after the expiration of the Validation Term without Tenaya's prior written consent. Alnylam may request that Tenaya utilize a Third Party Model in the Tenaya Research Activities, provided that the Parties will agree in writing in advance regarding the selection of the Third Party Model and the costs and expenses for such Third Party Model that will be reimbursed by Alnylam.

3.3.1***In Vitro*** **Validation Activities**. During the Validation Term, Tenaya will use the Tenaya Platform Technology to conduct *in vitro* assessments to validate the Alnylam Gene Targets (and, if needed, any Replacement Gene Target, if any) in accordance with the Research Plan and Research Budget ("***In Vitro*** **Validation Activities**"). Tenaya shall not be obligated to conduct *In Vitro* Validation Activities for more than [***] Alnylam Gene Targets without Tenaya's prior written consent. During the Validation Term, Tenaya shall conduct additional *In Vitro* Validation Activities with respect to each Collaboration Target at Alnylam's written request and at Alnylam's cost and expense.

3.3.2***In Vitro*** **Data Package**. Upon the completion of the *In Vitro* Validation Activities under the Research Plan with respect to each Collaboration Target, Tenaya will deliver to Alnylam a distinct data package including (a) the results of the *In Vitro* Validation Activities conducted by Tenaya with respect to such Collaboration Target under this Agreement and (b) any other Know-How, including information about the applicable Associated Primary Cardiovascular Indication, Controlled by Tenaya reasonably necessary or useful for Alnylam to determine whether to proceed to *in vivo* validation activities with respect to such Collaboration Target under the Research Plan (each such data package, an "***In Vitro*** **Data Package**").

3.3.3***In Vivo*** **Validation Activities**. Tenaya will conduct *in vivo* target validation using animal models in accordance with the Research Plan and Research Budget ("***In Vivo*** **Validation Activities**"). Alnylam will generate and deliver to Tenaya reasonable quantities of Alnylam Tool Compounds for each Collaboration Target for which Alnylam desires Tenaya to conduct such *In Vivo* Validation Activities. Tenaya will not (a) reverse engineer or otherwise analyze any Alnylam Tool Compound for the purpose of determining the sequence or structure thereof, (b) transfer the Alnylam Tool Compounds to any Third Party (except to permitted Subcontractors for the purpose of conducting *In Vivo* Validation Activities), or (c) use any Alnylam Tool Compound for any purpose other than the *In Vivo* Validation Activities.

3.3.4***In Vivo*** **Data Package**. Upon completion of the *In Vivo* Validation Activities under the Research Plan with respect to each Collaboration Target, Tenaya will deliver to Alnylam a distinct data package including (a) the results of the *In Vivo* Validation Activities conducted by Tenaya with respect to such Collaboration Target under this Agreement and (b) any other Know-How, including information about the applicable Associated Primary Cardiovascular Indication, controlled by Tenaya and reasonably necessary or useful for Alnylam to determine whether Alnylam should proceed and conduct further Development of such Collaboration Target (each such data package, an "***In Vivo*** **Data Package**").

3.3.5**Validation Term Expiration**. If, upon the expiration of the Validation Term (including any extended period for the completion of work under Section 3.3), Alnylam has not instructed Tenaya to start or continue the *In Vivo* Validation Activities with respect to a Non-Alnylam Collaboration Target, then such Non-Alnylam Collaboration Target shall cease to be a Collaboration Target (and shall be considered a Terminated Collaboration Target) upon the expiration of the Validation Term.

3.4 **Evaluation Term**. During the Evaluation Term for each Collaboration Target, at Alnylam's cost and expense, Alnylam will have the right to evaluate each Collaboration Target by conducting additional *in vitro* and *in vivo* animal studies and by evaluating and utilizing all data and information delivered by Tenaya to Alnylam for such Collaboration Target, in order to evaluate whether to further Develop Products Directed To such Collaboration Target. On a Non-Alnylam Collaboration Target-by-Non-Alnylam Collaboration Target basis, in the event Alnylam fails to commence an NHP PD Study prior to the expiration of the Evaluation Term for such Non-Alnylam Collaboration Target, then such Non-Alnylam Collaboration Target will be deemed a Terminated Collaboration Target and the license granted to Alnylam pursuant to Section 6.2 will terminate with respect to such Terminated Collaboration Target. For clarity, Alnylam will be free at all times during and after the Term of this Agreement, in its discretion, to evaluate each Alnylam Gene Target by conducting additional *in vitro* and *in vivo* animal studies and by evaluating and utilizing all data and information delivered by Tenaya to Alnylam for such Alnylam Gene Target, in order to evaluate whether to further Develop and Commercialize Products Directed To such Alnylam Gene Target.

4. PRODUCT DEVELOPMENT AND COMMERCIALIZATION.

4.1 **Development of Products**. Except as expressly set forth herein, for each Collaboration Target, for the Term of this Agreement, as between the Parties, Alnylam will have the sole right and responsibility, at its cost and expense, for the research and Development of Products Directed To a Collaboration Target in

the Field in the Territory (including having an Affiliate or, subject to Section 2.8 and Section 6.3, a Third Party, research and Develop on its behalf).

4.2 **Regulatory Matters**. Except with respect to Tenaya's responsibilities under Section 3.3, Alnylam will have sole right, responsibility and decision making authority with respect to regulatory matters for Products Directed To a Collaboration Target in the Field in the Territory, including the content of any regulatory filing or dossier, pharmacovigilance reporting, labeling, safety, and the decision to file or withdraw any IND or to cease or suspend any Clinical Trial. Alnylam will have sole responsibility for preparing and submitting all Regulatory Materials for such Products in the Field in the Territory, including preparing, submitting and holding all INDs and marketing authorization applications for Products. Tenaya will reasonably cooperate with Alnylam and provide to Alnylam all Know-How Controlled by Tenaya regarding any Collaboration Target, in each case as may be reasonably requested by Alnylam, in order to prepare or support any Regulatory Materials for Products Directed To a Collaboration Target in the Field in the Territory and interactions with any Regulatory Authority in connection with Development or Regulatory Approval of such Products. Tenaya will provide [***] free of charge for such cooperation and assistance, and Alnylam will reimburse Tenaya for all (a) Out-of-Pocket Costs and (b) FTE Costs (after such [***]), in each case ((a) and (b)) associated with such cooperation and assistance. Alnylam will own all Regulatory Materials for such Products and all such Regulatory Materials will be submitted in the name of Alnylam (or its Affiliate, Sublicensee or designee, as applicable).

4.3 **Commercialization**. For the Term of this Agreement, as between the Parties, Alnylam will have the sole right and responsibility, at its cost and expense, for the Commercialization of Products Directed To any Collaboration Target in the Field in the Territory (including having an Affiliate or, subject to Section 2.8 and Section 6.3, a Third Party, Commercialize on its behalf).

4.4 **Progress Reports**. Following the discontinuation of the JSC, Alnylam shall, on or before [***] of each year, provide Tenaya with a reasonably detailed annual written report summarizing Alnylam's progress in the Development of Licensed Products Directed To a Non-Alnylam Collaboration Target. Each progress report shall include a summary of pre-clinical and/or clinical development activities with respect to such Licensed Products during the preceding year.

4.5 **Standards of Conduct**. Each Party will perform, and will use reasonable efforts to ensure that its Affiliates, Sublicensees and Third Party contractors perform, its Development activities in good scientific manner, and in compliance in all material respects with the requirements of Applicable Law.

5. **GOVERNANCE**.

5.1 **Joint Steering Committee**. On the Effective Date, the Parties will establish a joint steering committee with the roles set forth in Section 5.2 (the "**Joint Steering Committee**" or "**JSC**") consisting of the [***] representatives from each Party set forth on **Schedule 5.1** with a co-chairperson from each Party. The JSC may change its size from time to time by mutual consent of both Parties, provided that the JSC will consist at all times of an equal number of representatives of each of Tenaya and Alnylam. Each Party may at any time appoint different JSC representatives or change its designated co-chairperson by written notice to the other Party. Other employees or consultants of a Party who are not the Alliance Managers of such Party or representatives of such Party on the JSC may attend meetings of the JSC with the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed; provided, however, that such attendees (a) will not vote or otherwise participate in the decision-making process of the JSC and

(b) are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 8.

5.2 **Responsibilities**. The JSC will be responsible for (a) reviewing the Tenaya Nominated Gene Targets (including for clarity Replacement Gene Targets) and Gene Targets nominated by Alnylam and compiling the Collaboration Target List, (b) overseeing the activities under the Research Plan through the completion of the Validation Term, (c) serving as an information-sharing forum during the period beginning upon the completion of the Validation Term until the completion of the Evaluation Term, (d) approving any changes and updates to the Research Plan (including the Research Budget), and (e) monitoring, reviewing and recording of the progress of the Research Plan.

5.3 **Decisions**. Decisions of the JSC will be by unanimous vote, with each Party having collectively one (1) vote, provided that if, after attempts to amicably resolve any disagreement at the JSC, the Parties are unable to agree on a matter to be decided by the JSC, [***] after escalation to Executive Officers in accordance with Section 13.12; provided further that, (a) [***], and (b) [***].

5.4 **JSC Meetings**. The JSC will hold meetings at such times and places as the co-chairpersons may determine. The JSC will meet at least [***] during the Validation Term and thereafter during the Evaluation Term on an ad hoc basis as reasonably requested by Alnylam until discontinuation of the JSC in accordance with Section 5.8. The meetings of the JSC need not be in person and may be by telephone or any other method determined by the JSC. Each Party will bear its own costs associated with attending such meetings, including any costs relating to travel or such Party's participation in such meetings. Each Party will be responsible for all of its own costs and expenses of participating in the JSC. Either Party's representatives on the JSC may call a special meeting of the JSC upon at least [***] prior written notice, except that emergency meetings may be called with at least [***] prior written notice. The Alliance Managers will be responsible for preparing and circulating an agenda in advance of each meeting.

5.5 **Minutes**. The Parties will alternate responsibility for preparing and circulating minutes of each meeting of the JSC, setting forth, inter alia, an overview of the discussions at the meeting and a list of any actions, decisions or determinations approved by the JSC. Such minutes will be effective only after such minutes have been approved by both Parties in writing. Definitive minutes of all JSC meetings will be finalized no later than [***] after the meeting to which the minutes pertain.

5.6 **Limitations on Authority of the JSC**. The JSC will have solely the roles and responsibilities assigned to it in this Article 5. The JSC will have no authority to (a) amend, alter or modify, or determine or waive compliance by a Party with, a Party's obligations under this Agreement, or (b) make any decision that is expressly stated in this Agreement to require the mutual agreement of the Parties or the consent of one Party against which such decision will be made. For avoidance of doubt, the JSC will have no authority with respect to Alnylam Gene Targets or Products.

5.7 **Alliance Managers**. Each Party will appoint a representative who possesses a general understanding of this Agreement and pharmaceutical research, clinical, regulatory, manufacturing and commercialization matters and who will oversee contact between the Parties for all matters between meetings of the JSC (each an "**Alliance Manage**r"). Each Party may replace its Alliance Manager at any time by notice in writing to the other Party.

5.8 **Discontinuation of JSC**. The JSC will exist from the Effective Date until the expiration of the Evaluation Term; provided that after the end of the Validation Term, the JSC will primarily serve as an

information-sharing body. Thereafter, the JSC will have no further roles or responsibilities under this Agreement.

6. LICENSES.

6.1 **Grants to Tenaya**. Subject to the terms and conditions of this Agreement, Alnylam hereby grants to Tenaya, during the Validation Term, a non-exclusive, non-transferable (except as permitted by Section 13.1), fully paid-up, worldwide, non-sublicensable (except to permitted Subcontractors) license under the Alnylam Know-How and Alnylam Patents to perform the Tenaya Research Activities in accordance with the Research Plan and Research Budget.

6.2 **Grants to Alnylam**. On a Collaboration Target-by-Collaboration Target basis, Tenaya grants to Alnylam an exclusive worldwide license, with the right to grant sublicenses through multiple tiers, under the Licensed Technology to evaluate and utilize such Collaboration Target and to research, Develop, manufacture, Commercialize or otherwise Exploit any Product Directed To such Collaboration Target in the Field in the Territory; provided that, subject to Tenaya's exclusivity obligations under Section 6.6 with respect to the Non-Alnylam Collaboration Targets, Tenaya will retain the right to use the generalized results from the Tenaya Research Activities for the purpose of generally enhancing or improving the Tenaya Platform Technology.

6.3 **Sublicenses**. Alnylam will have the right to grant sublicenses, through multiple tiers, under the licenses granted to Alnylam in Section 6.2, as applicable, provided that each sublicense (a) is pursuant to a written agreement consistent with and subject to the terms and conditions of this Agreement, and (b) contains a requirement that the Sublicensee comply with confidentiality and non-use provisions that are no less restrictive than those set forth in Article 8 with respect to Tenaya's Confidential Information. Notwithstanding any sublicense to a Sublicensee, Alnylam will remain responsible to Tenaya for the performance of all of Alnylam's obligations under, and compliance with, all applicable terms and conditions of, this Agreement, including any obligations delegated to its Sublicensees. Alnylam shall provide Tenaya with written notice of any grant of sublicense to a Sublicensee of the rights and licenses granted to Alnylam in Section 6.2 no later than [***] following any such grant.

6.4 **No Implied License; Retention of Rights**. Except as expressly provided herein, nothing in this Agreement grants either Party or vests in either Party any right, title or interest in and to the Know-How, Patent Rights, Confidential Information, Trademarks or other intellectual property of the other Party (either expressly or by implication, estoppel or otherwise), other than the license rights expressly granted hereunder and the assignments expressly made hereunder. Neither Party will practice or otherwise exploit the Know-How, Patent Rights, Confidential Information, Trademarks or other intellectual property of the other Party outside the scope of the license rights expressly granted hereunder and the assignments expressly made hereunder. Without limiting the foregoing, nothing in this Agreement shall be deemed to grant (a) Alnylam any license or right to access the Tenaya Platform Technology or to otherwise use the Tenaya Platform Technology for any purpose whatsoever or (b) Tenaya any license or right of access to Alnylam Gene Targets, Confidential Information of Alnylam, or Alnylam Collaboration Technology other than as expressly set forth in this Agreement.

6.5 **Bankruptcy**. If this Agreement is rejected by a Party as a debtor under Section 365 of the United States Bankruptcy Code (or similar provision in the bankruptcy laws of another jurisdiction), then, notwithstanding anything else in this Agreement to the contrary, all licenses and rights to licenses granted under or pursuant to this Agreement by the Party in bankruptcy to the other Party are, and will otherwise

be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (or similar provision in the bankruptcy laws of the jurisdiction), licenses of rights to "intellectual property" as defined under Section 101(35A) of the United States Bankruptcy Code (or similar provision in the bankruptcy laws of the jurisdiction).

6.6 **Exclusivity**.

6.6.1 During the Term, on a Non-Alnylam Collaboration Target-by-Non-Alnylam Collaboration Target basis, except in connection with the conduct of activities under the Research Plan, Tenaya shall not, itself or with any Third Party, conduct any research or Development activities with respect to (a) such Non-Alnylam Collaboration Target or (b) any therapeutic product designed to be Directed To such Non-Alnylam Collaboration Target, in each case for so long as such Non-Alnylam Collaboration Target remains a Collaboration Target.

6.6.2 If there is a Change of Control of Tenaya, the obligations of Section 6.6.1 will not preclude the Acquirer or any of its Affiliates (other than Tenaya or any Person that was an Affiliate of Tenaya prior to such Change of Control or any successor entity to Tenaya or any such Affiliates of Tenaya) from exploiting any program, compound or product of the Acquirer; provided that [***].

7. **FINANCIAL TERMS**.

7.1 **Platform Access Fee**. As partial consideration for the licenses and other rights granted by Tenaya to Alnylam under this Agreement, Alnylam will pay to Tenaya a one-time, non-creditable, non-refundable technology access fee of the amount calculated as follows: Ten Million Dollars ($10,000,000) minus any $500,000 reduction(s), if any, pursuant to Section 3.2.4 for Rejected Gene Targets (such calculated amount, the "**Platform Access Fee**"). Tenaya will send Alnylam an invoice for the Platform Access Fee on or after the Collaboration Target List Finalization Date and Alnylam will pay such amount within thirty (30) days after Alnylam's receipt of such invoice.

7.2 **Development and Regulatory Milestone Payments**.

7.2.1 **Development and Regulatory Milestone Events**. Subject to the terms of this Section 7.2, Alnylam will notify Tenaya promptly (but in all cases within [***]) following the first achievement by Alnylam or its Affiliate or Sublicensee of each milestone event described below in this Section 7.2.1 (each, a "**Development and Regulatory Milestone**") with respect to, on a Non-Alnylam Collaboration Target-by-Non-Alnylam Collaboration Target basis, the first Licensed Product that: (a) is Directed To any Tenaya Gene Target, Overlapping Gene Target, or Selected Non-Novel Gene Target, as applicable, and (b) is being studied or has Regulatory Approval for a Primary Cardiovascular Indication, to achieve such milestone event, and shall pay Tenaya the corresponding non-creditable, non-refundable milestone payment:

	Development and Regulatory Milestone Event	First Product Directed To [***]	First Product Directed To [***]
1	[***]	[***]	[***]
2	[***]	[***]	[***]
3	[***]	[***]	[***]
4	[***]	[***]	[***]
5	[***]	[***]	[***]
6	[***]	[***]	[***]

7.2.2**Maximum Development and Regulatory Milestone Payments**. In no event will the aggregate Development and Regulatory Milestone payments pursuant to Section 7.2.1 exceed: (a) with respect to each [***], [***], (b) with respect to each [***], [***], or (c) with respect to each [***], [***], in each case ((a) through (c)) irrespective of the number of Licensed Products that achieve such Development and Regulatory Milestone. For example, [***]. For clarity, no Development and Regulatory Milestone payments will be due to Tenaya for any Product Directed To an Alnylam Gene Target. [***].

7.2.3**Development and Regulatory Milestone Payment Reduction**. [***].

7.3 **Sales Milestones**.

7.3.1**Sales Milestone Events**. Subject to the terms of this Section 7.3, Alnylam will notify Tenaya promptly (but in all cases within [***] after the Calendar Quarter during which the applicable milestone event is achieved) following the first achievement by a Selling Party of each milestone event described below in this Section 7.3.1 (each, a "**Sales Milestone**") with respect to, on a Non-Alnylam Collaboration Target-by-Non-Alnylam Collaboration Target basis, aggregate Net Sales of all Licensed Products Directed To such Tenaya Gene Target, Overlapping Gene Target, or Selected Non-Novel Gene Target, as applicable, that has Regulatory Approval for a Primary Cardiovascular Indication, to achieve such milestone event, and shall pay Tenaya the corresponding non-creditable, non-refundable milestone payment:

	Sales Milestone Event	Licensed Products Directed To [***]	Licensed Products Directed To [***]
1	Aggregate Net Sales of all Licensed Products Directed To a given Non-Alnylam Collaboration Target in the Territory in a Calendar Year [***]	[***]	[***]
2	Aggregate Net Sales of all Licensed Products Directed To a given Non-Alnylam Collaboration Target in the Territory in a Calendar Year [***]	[***]	[***]

3	Aggregate Net Sales of all Licensed Products Directed To a given Non-Alnylam Collaboration Target in the Territory in a Calendar Year [***]	[***]	[***]
4	Aggregate Net Sales of all Licensed Products Directed To a given Non-Alnylam Collaboration Target in the Territory in a Calendar Year [***]	[***]	[***]

7.3.2**Maximum Sales Milestone Payments**. In no event will the aggregate Sales Milestone payments pursuant to Section 7.3.1 exceed: (a) with respect to each [***], [***], (b) with respect to each [***], [***], or (c) with respect to each [***], [***], in each case ((a) through (c)) irrespective of the number of times achieved. For example, [***]. For clarity, no Sales Milestone payments will be due to Tenaya for any Product Directed To an Alnylam Gene Target. If more than one (1) Sales Milestone is first achieved in a given Calendar Year, Alnylam shall pay to Tenaya the applicable milestone payments for each such Sales Milestone.

7.3.3**Sales Milestone Payment Reduction**. [***].

7.4 **Payment Method and Currency**. All payments under this Agreement will be made in immediately available funds to an account designated by Tenaya. All sums due under this Agreement will be payable in Dollars. Upon the notice by Alnylam of the achievement of any Development and Regulatory Milestone or Sales Milestone, Tenaya will send Alnylam an invoice for the amount due and Alnylam will pay such amount within [***] after Alnylam's receipt of such invoice.

7.5 **Taxes**.

7.5.1**General**. Each Party will be responsible for all taxes imposed on such Party's net income, or on net income allocated to such Party under Applicable Law. To the extent one Party pays (pursuant to a legal requirement) taxes imposed on net income of the other Party, the other Party will reimburse the paying Party for any such taxes paid. The amounts payable pursuant to this Agreement will not be reduced on account of any taxes unless required by Applicable Law.

7.5.2**Indirect taxes**. It is understood and agreed between the Parties that all amounts to be paid pursuant to this Agreement are exclusive of any value-added tax ("**VAT**") and other indirect tax (customs duties, sales, use or excise taxes and similar indirect taxes). If any VAT or other indirect tax should apply to the payments by Alnylam under this Agreement, Alnylam shall pay VAT or any other indirect tax at the applicable rate in addition to any such payments following the receipt of a valid VAT or other indirect tax invoice in accordance with local law, issued by Tenaya in respect of those payments. Where such VAT or other indirect tax is incorrectly charged to Alnylam, Tenaya shall either issue a credit invoice or reimburse Alnylam in an amount that equals such incorrectly charged VAT or other indirect tax amount.

7.5.3**Withholding Taxes**. Tenaya will bear any and all withholding taxes levied on Tenaya on account of all payments it receives under this Agreement. Alnylam may withhold from payments

due to Tenaya amounts for payment of any withholding tax that is required by Applicable Law to be paid to any taxing authority with respect to such payments. In such case, Alnylam will promptly provide to Tenaya all relevant documents and information relating to such withholding tax, including and to the extent necessary, original receipts or other evidence reasonably desirable and sufficient to allow Tenaya to document such withholding tax for the purposes of reclaiming the withholding taxes or claiming foreign tax credits or similar benefits. The Parties will cooperate with each other in reducing withholding taxes under any double taxation or other similar treaty or agreement from time to time in force and Tenaya will provide Alnylam, as of the date hereof (and at any such time its status changes for purposes hereof or such form expires), any such IRS Form W-9 or W-8 it is eligible to provide to reduce the rate of withholding hereunder. Notwithstanding anything herein to the contrary, to the extent Alnylam fails to withhold pursuant to this Section 7.5.3 in respect of any payment under this Agreement and a taxing authority subsequently asserts that withholding was required, Tenaya will indemnify and hold harmless Alnylam for any such payments Alnylam is required to pay to such taxing authority. All payments hereunder shall be made by Alnylam from an entity resident in the United States. The provisions of this Section 7.5.3 are intended to apply only if any payment under this Agreement becomes subject to withholding taxes in the future. Notwithstanding the foregoing, the Parties acknowledge and agree that if Alnylam (or its Affiliates, successor or assignee) is required to make a payment to Tenaya subject to deduction or withholding of taxes, as described in this Section 7.5.3, and if the obligation to deduct or withhold taxes arises, or if the amount of such taxes required to be deducted or withheld is increased solely as a result of any action taken by Alnylam (or its Affiliates or a successor or assignee), including the assignment or transfer of this Agreement by Alnylam pursuant to Section 13.1 or otherwise, or there is a change, whether by corporate continuance, merger or other means, in the tax residency of Alnylam (each, a "**Withholding Tax Action**"), then notwithstanding anything to the contrary herein, if Alnylam (or its Affiliates, successor or assignee) is required to deduct or withhold taxes from any payment to Tenaya as a result of a Withholding Tax Action, Alnylam shall increase the amount of such payment only to the extent necessary to ensure that Tenaya receives the same net amount that it would have received without such Withholding Tax Action, provided that such increase shall apply solely to the extent that such withholding taxes constitute a final, non-creditable and non-refundable tax cost to Tenaya.

7.6 **Resolution of Payment Disputes**. In the event there is a dispute relating to any payment obligations or reports hereunder, the Party with the dispute will provide the other Party with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties will seek to resolve the dispute as promptly as possible, but no later than [***] after such written notice is received. If the Parties are unable to resolve such payment dispute within such period then the matter will be resolved pursuant to Section 13.12. The Parties agree that if there is a dispute regarding any payment amount, only the disputed amount will be withheld from the payment, and the undisputed amount will be paid within the applicable timeframes.

7.7 **Late Payments**. If any payment properly due under this Agreement and not subject to a good faith dispute is not paid when due in accordance with the applicable provisions of this Agreement, the payment shall accrue interest at the rate equal to [***], or the maximum rate allowable by Applicable Law, whichever is less.

7.8 **Record-Keeping; Audits**. Each Party will keep (and will cause its Affiliates and its Sublicensees to keep) complete and accurate books and records pertaining to (a) in the case of Alnylam, the Net Sales of Licensed Products (the "**Alnylam Records**") and (b) in the case of Tenaya, all FTEs utilized and Out-of-Pocket Costs incurred in connection with the performance of the Tenaya Research Activities and any other

amounts to be reimbursed by Alnylam under this Agreement (the "**Tenaya Records**"), in each case ((a) and (b)), in reasonable detail to permit the other Party to confirm the accuracy of all payments or costs reported. Such records shall be kept for [***] (or such longer period as required by Applicable Law) following the end of the Calendar Quarter to which they pertain. Upon reasonable request, but in any case no less than [***] advance notice by one Party (the "**Auditing Party**") to the other Party (the "**Audited Party**") and not more than once in each Calendar Year and once per audited period (in each case, except for cause), the Audited Party and its Affiliates will permit an independent certified public accounting firm of nationally recognized standing in the United States, selected by the Auditing Party and reasonably acceptable to the Audited Party, to have access during normal business hours to such of the records of the Audited Party and its Affiliates and, if applicable, their Sublicensees, as may be reasonably necessary to verify the accuracy of (i) in the case of Alnylam as the Audited Party, the applicable Alnylam Records and the payments amounts owed to Tenaya hereunder, and (ii) in the case of Tenaya as the Audited Party, the Tenaya Records and all FTEs utilized and Out-of-Pocket Costs reported to have been incurred in connection with the performance of the Tenaya Research Activities, for any year ending not more than [***] prior to the date of such request. The accounting firm will enter a confidentiality agreement reasonably acceptable to the Audited Party governing the use and disclosure of the Audited Party's information disclosed to such firm, and such firm will disclose to the Auditing Party only whether information provided by the Audited Party to the Auditing Party as described in clauses (a) and (b) above was accurate and the specific details concerning any discrepancies, which information will be Confidential Information of the Audited Party. Either Party may refer any disputes with respect to the findings of such accounting firm for resolution in accordance with the dispute resolution procedures set forth in Section 13.12. If either Party is found to have been underpaid any amounts payable to such Party hereunder then such Party will be entitled to recover any undisputed discrepancy, together with interest calculated pursuant to Section 7.7, no later than [***] after delivery to the Parties of the final report of such accounting firm. If either Party is found to have overpaid any amounts payable to the other Party, such Party shall credit the amount of the overpayment against future payments payable to the other Party (and if no further payments are due, shall be refunded by the other Party within [***] of request). The fees charged by such accounting firm will be paid by the Auditing Party; provided that if the audit discloses a net underpayment of amounts owed or overreporting of expenses by the Audited Party of more than [***], then, [***], the Audited Party will pay the reasonable fees and expenses charged by such accounting firm. The Auditing Party will treat all financial information disclosed by its accounting firm pursuant to this Section 7.8 as Confidential Information of the Audited Party for purposes of this Agreement.

8. CONFIDENTIALITY AND PUBLICATION.

8.1 Nondisclosure and Non-Use Obligations.

8.1.1 **Confidential Information**. For purposes of this Agreement, "**Confidential Information**" means, with respect to a Party, any and all confidential or proprietary information and data, and all other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, including information of Third Parties, whether communicated in writing or orally or by any other method, which is provided by one Party (the "**Disclosing Party**") to the other Party (the "**Receiving Party**") in connection with this Agreement; provided that (a) [***], will at all times be considered Confidential Information of Alnylam as if Alnylam were the Disclosing Party with respect thereto and there will be no restriction on Alnylam's use or disclosure of the [***], and (b) [***] will be considered Confidential Information of each Party until the expiration of the Evaluation Term. Upon the expiration of the applicable Evaluation Term, (i) in the event that Alnylam had not commenced an NHP PD Study with respect to a particular

Non-Alnylam Collaboration Target prior to the expiration of the applicable Evaluation Term, the [***] with respect to the applicable Non-Alnylam Collaboration Target will be the Confidential Information of Tenaya and will no longer be the Confidential Information of Alnylam and (ii) in the event that Alnylam has commenced an NHP PD Study with respect to a particular Non-Alnylam Collaboration Target prior to the expiration of the Evaluation Term, the [***] with respect to the applicable Non-Alnylam Collaboration Target will be the Confidential Information of Alnylam and will no longer the Confidential Information of Tenaya; provided that, upon the termination (but not expiration) of the Agreement, such Non-Alnylam Collaboration Target Information disclosed by Tenaya to Alnylam will be the Confidential Information of Tenaya and will no longer be the Confidential Information of Alnylam. Notwithstanding anything to the contrary under this Agreement, Tenaya Platform Technology will be the Confidential Information of Tenaya (and not Alnylam).

The Parties agree that all information disclosed pursuant to the Confidentiality Agreement (x) by Alnylam, shall be deemed to be Confidential Information of Alnylam hereunder and subject to the terms of this Agreement, and (y) by Tenaya, shall be deemed to be the Confidential Information of Tenaya hereunder and subject to the terms of this Agreement.

8.1.2**Obligations**. At all times during the Term and for a period of [***] following termination or expiration hereof in its entirety, each Receiving Party will, and will cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the Disclosing Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or is necessary or reasonably useful for the performance of, or the exercise of such Party's rights under, this Agreement. Notwithstanding the foregoing, the confidentiality and non-use obligations under this Section 8.1 with respect to any Confidential Information will not include any information that:

(i) is known by the Receiving Party at the time of its receipt, without an obligation of confidentiality, and not through a prior disclosure by the Disclosing Party, as demonstrated by the Receiving Party's business records, documentation or other competent proof;

(ii) is in the public domain or publicly known by use and/or publication before its receipt from the Disclosing Party (or, with respect to the Association of a Gene Target with the modulation of disease phenotype for a given indication, before identification or discovery of such Association hereunder), or thereafter enters the public domain or becomes publicly known through no fault of the Receiving Party;

(iii) is subsequently disclosed to the Receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the Disclosing Party; or

(iv) is independently developed by the Receiving Party without use of or reference to the Disclosing Party's Confidential Information, as demonstrated by the Receiving Party's business records, documentation or other competent written proof.

Specific aspects or details of Confidential Information will not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is

embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information will not be considered to be in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

8.1.3Notwithstanding the obligations of confidentiality and non-use set forth in this Section 8.1, a Receiving Party may provide Confidential Information disclosed to it, and disclose the existence and terms of this Agreement, (i) as may be reasonably required in order to perform its obligations and to exploit its rights under this Agreement, to Affiliates and, with respect to Alnylam, Sublicensees, and its or their employees, directors, agents, consultants, advisors and/or other Third Parties who have a need to know such Confidential Information for the performance of its obligations hereunder (or for such entities to determine their interest in performing such activities) in accordance with this Agreement, in each case who are obligated in writing to keep such Confidential Information confidential on terms no less stringent than those in this Section 8.1; (ii) Regulatory Authorities or other Governmental Authorities in order to obtain marketing approval for Products Directed To a Collaboration Target or prosecute or maintain patents in accordance with this Agreement, or otherwise perform its obligations or exploit its rights under this Agreement; provided, that such Confidential Information will be disclosed only to the extent reasonably necessary to do so; (iii) the extent required by law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity; (iv) any bona fide actual or prospective underwriters, investors, lenders, other financing sources, acquirers, collaborators or strategic partners and to consultants and advisors of such parties who have a need to know such Confidential Information, in each case who are obligated in writing to keep such Confidential Information confidential on terms no less stringent than those in this Section 8.1 (except, solely with respect to banks, lenders and other financing sources, the duration of such obligations may be shorter but shall be customary for the type of disclosure, provided that the Receiving Party has used reasonable efforts to negotiate the same duration as this Section 8.1 and in no event shall the duration of such obligations be less than [***]); and (v) the extent necessary for a Party to prosecute and maintain Patent Rights in accordance with Section 11.4 or to make any regulatory submissions and other filings with Governmental Authorities (including Regulatory Authorities) related to the Exploitation of a Product Directed To a Collaboration Target.
If a Party is required by a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law to disclose Confidential Information that is subject to the non-disclosure provisions of this Section 8.1 or Section 8.2, such Party will, to the extent permitted by law, promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations and assist the other Party in such endeavors. Confidential Information that is required to be disclosed in response to such court or governmental order or as required by Applicable Law will remain otherwise subject to the confidentiality and non-use provisions of this Section 8.1 and Section 8.2. If either Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or any stock exchange or listing entity, such Party will provide the other Party with a copy of this Agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, will provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions, and will take such Party's reasonable and timely comments into consideration before filing the Agreement.

8.2 **Publication and Publicity**.

8.2.1 **Publication**. As between the Parties, Alnylam will have the sole right, in consultation with Tenaya, to issue and control all publications in scientific journals and make scientific presentations related to the Collaboration Targets, the association between a Collaboration Target and the applicable Primary Cardiovascular Indication and any Products (for clarity, prosecution and maintenance of Patent Rights and the associated publication shall be governed by Section 11.4). In any event, Alnylam will not issue any publications or presentations that disclose any Tenaya Confidential Information or that discuss the Tenaya Platform Technology without Tenaya's prior written consent. Any publication will include recognition of the contributions of Tenaya according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate. Without limiting the foregoing, for any such publications and presentations that specifically reference any Non-Alnylam Collaboration Target and a Primary Cardiovascular Indication, Alnylam shall: (a) provide Tenaya with a draft of such publication or presentation at least [***] prior to submission to the publisher; (b) remove any Confidential Information of Tenaya, as requested by Tenaya; and (c) if requested by Tenaya, delay the submission for publication of such publication or presentation of such presentation, as applicable, for an additional [***] to seek patent protection with respect to the content relating to the Tenaya Platform Technology of such publication or presentation in accordance with Section 11.4.

8.2.2 **Publicity**.

(a) Except as set forth in Section 8.1 and clause (b) below, the terms of this Agreement may not be disclosed by either Party, and no Party will use the name, trademark, trade name or logo of the other Party or its employees in any publicity, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by law or expressly permitted by the terms of this Agreement.

(b) On or promptly after the Effective Date, Tenaya will issue a press release announcing the execution of this Agreement in the form attached hereto as **Schedule 8.2.2**. Except as provided in Sections 8.1 or 8.2, neither Party will issue a press release or public announcement relating to this Agreement without the prior written approval of the other Party, which approval will not be unreasonably withheld, conditioned or delayed, except that a Party may, (i) once a press release or other public statement is approved in writing by both Parties, make subsequent public disclosure of the information contained in such press release or other written statement without the further approval of the other Party, and (ii) issue a press release or public announcement as required, in the reasonable judgment of such Party, by law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity.

(c) Alnylam and its Affiliates and Sublicensees may make public announcements or disclosures reasonably necessary or useful to Develop or Commercialize Products Directed To a Collaboration Target in the Field in the Territory, including disclosures necessary to recruit subjects to Clinical Trials and disclosures to advertise, promote and otherwise Commercialize such Products.

9. **REPRESENTATIONS, WARRANTIES AND COVENANTS**.

9.1 **Mutual Representations and Warranties**. Each Party hereby represents and warrants to the other Party that as of the Effective Date:

9.1.1 It is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement, and to carry out the provisions hereof.

9.1.2 It is duly authorized to execute and deliver this Agreement, and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action.

9.1.3 This Agreement is legally binding upon it and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by the representing and warranting Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party and by which it may be bound, or with its charter or by-laws.

9.1.4 It has not granted, and will not grant, during the Term, any right to any Affiliate or Third Party that would conflict with the rights granted to the other Party hereunder.

9.2 **Representations and Warranties of Tenaya**. Tenaya represents and warrants to Alnylam that as of the Effective Date:

9.2.1 Except for agreements with vendors or services providers that are entered into in the ordinary course of business where certain intellectual property rights may have been non-exclusively licensed to Tenaya or its Affiliates for Tenaya to exploit the deliverables under such agreements and such non-exclusive licenses are incidental to such agreements, Tenaya is the sole and exclusive owner of, or otherwise Controls, the Tenaya Technology, and all of the Licensed Technology is solely and exclusively owned by Tenaya and is free and clear of liens, charges or encumbrances other than licenses and rights granted to Third Parties that are not inconsistent with the rights and licenses granted to Alnylam under this Agreement.

9.2.2 Tenaya has sufficient legal or beneficial title and ownership of, or sufficient license rights under, the Licensed Technology to grant the licenses to such Licensed Technology granted to Alnylam pursuant to this Agreement. Tenaya does not possess or Control any Tenaya Platform Technology which, absent a license to Alnylam, would be infringed by the evaluation and utilization of the Collaboration Targets or the Exploitation of Products by Alnylam under the licenses to Licensed Technology granted to Alnylam under Section 6.2 as contemplated under this Agreement. Tenaya has the right to practice the Tenaya Platform Technology in conducting the Tenaya Research Activities as contemplated as of the Effective Date.

9.2.3 To Tenaya's knowledge, Tenaya does not possess any information as of the Effective Date from which it may be reasonably concluded that the Exploitation of the Tenaya Technology as contemplated under this Agreement, infringes any issued Patent Right of any Third Party or misappropriates any trade secrets, know-how or similar rights or property of any Third Party.

9.2.4 There is no (a) claim, demand, suit, proceeding, arbitration, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or, to Tenaya's

knowledge, threatened against Tenaya or any of its Affiliates or (b) judgment or settlement against or owed by Tenaya or any of its Affiliates, in each case ((a) and (b)), in connection with the Tenaya Technology, as of the Effective Date, including any claim alleging that the issued patents in the Tenaya Patents are invalid or unenforceable.

9.2.5To Tenaya's knowledge, the conception, development and reduction to practice of the Tenaya Technology, as it exists on the Effective Date, have not constituted or involved the infringement of any intellectual property rights, misappropriation of trade secrets or know-how or otherwise violate similar rights or property of any person.

9.2.6To Tenaya's knowledge, no Third Party is infringing, misappropriating, or otherwise violating, or threatening to infringe, misappropriate, or otherwise violate, the Tenaya Technology.

9.2.7There are no agreements between Tenaya and a Third Party entered into prior to the Effective Date pursuant to which Tenaya has transferred or transfers aspects of the Tenaya Technology to such Third Party for such Third Party's use independent of Tenaya involvement in the discovery and development of Gene Targets therefrom.

9.2.8There is no agreement between Tenaya and a Third Party entered into prior to the Effective Date pursuant to which Tenaya receives a license or grant of any right to Patent Rights or Know-How included in the Licensed Technology that are necessary or reasonably useful to the practice of the Licensed Technology as contemplated in this Agreement, excluding for agreements with vendors or services providers that are entered into in the ordinary course of business where certain intellectual property rights may have been non-exclusively licensed to Tenaya or its Affiliates for Tenaya to exploit the deliverables under such agreements and such non-exclusive licenses are incidental to such agreements.

9.2.9Tenaya and its Affiliates have taken measures necessary to protect the secrecy, confidentiality, and value of the Know-How included in the Tenaya Technology that constitutes trade secrets under Applicable Law (including requiring all employees, consultants, and independent contractors to execute binding and enforceable agreements requiring all such employees, consultants, and independent contractors to maintain the confidentiality of such Know-How included in the Tenaya Technology).

For clarity, Tenaya does not make any representation or warranty with respect to any Alnylam Gene Targets.

9.3 **Debarment**. Neither Party nor, to such Party's knowledge, any individual or organization providing services on its behalf in connection with this Agreement has ever been debarred under 21 U.S.C. §335a, disqualified under 21 C.F.R. §312.70 or §812.119, sanctioned by a Federal Health Care Program (as defined in 42 U.S.C §1320 a-7b(f)), including without limitation the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any other similar Federal or state agency or program or comparable laws in any other country or jurisdiction. In the event that either Party or any individual or organization providing services on its behalf receives notice of debarment, suspension, sanction, exclusion, ineligibility or disqualification under the above-referenced statutes, such Party shall immediately notify the other Party in writing.

9.4 **Covenants**. In addition to the covenants made elsewhere in this Agreement.

9.4.1Each Party hereby covenants to the other Party that during the Term, it will not enter into any agreement with a Third Party that is inconsistent with or would preclude the rights granted hereunder;

9.4.2Tenaya hereby covenants to Alnylam that during the Term, it will not enter into any agreement or arrangement which limits the ownership rights of Alnylam with respect to, or limits the ability of Alnylam to grant a license, sublicense or access, or provide access or other rights in, to or under, any intellectual property right or material (including any Patent Rights, Know-How or other data or information), in each case, that would, but for such agreement or arrangement, be included in the exclusive rights licensed or assigned to Alnylam pursuant to this Agreement; and

9.4.3Each Party hereby covenants to the other Party that it will maintain valid and enforceable agreements during the Term with all personnel acting by or on its behalf under this Agreement which require such personnel to assign to it their entire right, title and interest in and to all intellectual property rights to the extent necessary to effect ownership of such intellectual property rights as set forth in Section 11.2.

9.5 **Warranty Disclaimer**. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY KNOW-HOW, PATENT RIGHTS, COLLABORATION TARGET, PRODUCT, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF THE PRODUCTS PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL OR THAT ANY PARTICULAR SALES LEVEL WITH RESPECT TO THE PRODUCTS WILL BE ACHIEVED.

10. **INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE**.

10.1 **General Indemnification by Tenaya**. Tenaya hereby agrees to indemnify and hold Alnylam harmless, and defend Alnylam, its Affiliates and Sublicensees, and their respective directors, officers, employees and agents ("**Alnylam Indemnitees**") from and against any and all Third Party claims, suits, losses, liabilities, damages, costs, fees and expenses (including reasonable attorneys' fees) (collectively, "**Losses**") to the extent such Losses arise out of or result from, directly or indirectly, (a) any breach of, or inaccuracy in, any representation or warranty made by Tenaya in this Agreement or any breach or violation of any covenant or agreement of Tenaya in this Agreement, or (b) the negligence or willful misconduct by or of Tenaya and its Affiliates, and their respective directors, officers, employees and agents, in the performance of Tenaya's obligations under this Agreement. Tenaya will have no obligation to indemnify the Alnylam Indemnitees to the extent that the Losses arise out of or result from, directly or indirectly, any breach of, or inaccuracy in, any representation or warranty made by Alnylam in this Agreement, or any breach or violation of any covenant or agreement of Alnylam in this Agreement, or the negligence or willful misconduct by or of any of the Alnylam Indemnitees.

10.2 **General Indemnification by Alnylam**. Alnylam hereby agrees to indemnify and hold Tenaya harmless, and defend Tenaya, its Affiliates and their respective directors, officers, employees and agents

("**Tenaya Indemnitees**") from and against any and all Losses to the extent such Losses arise out of or result from, directly or indirectly, (a) any breach of, or inaccuracy in, any representation or warranty made by Alnylam in this Agreement or any breach or violation of any covenant or agreement of Alnylam in this Agreement, (b) the negligence or willful misconduct by or of Alnylam and its Affiliates, and their respective directors, officers, employees and agents, in the performance of Alnylam's obligations under this Agreement, or (c) the Development, manufacture, Commercialization or other Exploitation of Products by Alnylam or its Affiliates or Sublicensees (other than [***]). Alnylam will have no obligation to indemnify the Tenaya Indemnitees to the extent that the Losses arise out of or result from, directly or indirectly, any breach of, or inaccuracy in, any representation or warranty made by Tenaya in this Agreement, or any breach or violation of any covenant or agreement of Tenaya in this Agreement, or the negligence or willful misconduct by or of any of the Tenaya Indemnitees.

10.3 **Indemnification Procedure**. Each of the foregoing agreements to indemnify is conditioned on the relevant Alnylam Indemnitees or Tenaya Indemnitees (a) providing prompt written notice of any Third Party claim giving rise to an indemnification obligation hereunder; provided, however, that any delay or failure to provide such notice shall relieve the indemnifying Party of its obligations under this Article 10 only to the extent it is materially prejudiced by such delay or failure; (b) permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such Third Party claim (but only to the extent and for such period of time as such indemnifying Party agrees in writing with such indemnified Party that the indemnifying Party will be solely responsible for any and all such monetary damages), (c) providing reasonable assistance in the defense of such claim at the indemnifying Party's reasonable expense, and (d) not compromising or settling such Third Party claim without the indemnifying Party's advance written consent. If the Parties cannot agree as to the application of Section 10.1 and Section 10.2, each may conduct separate defenses of the Third Party claim, and each Party reserves the right to claim indemnity from the other in accordance with this Article 10 upon the resolution of the underlying Third Party claim.

10.4 **Limitation of Liability**. NEITHER PARTY HERETO WILL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, EXCEPT AS A RESULT OF A PARTY'S GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR A MATERIAL BREACH OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS IN ARTICLE 8 OR A BREACH OF THE EXCLUSIVITY PROVISION IN SECTION 6.6. NOTHING IN THIS SECTION 10.4 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY.

10.5 **Insurance**. Each Party will, at its own expense, procure and maintain during the Term and for a period of five years thereafter, insurance policies with insurers maintaining a rating of at least [***] adequate to cover its obligations hereunder and that are consistent with normal business practices of prudent companies similarly situated, including Cyber liability insurance (in an amount not less than [***] per occurrence), workers compensation, and product liability insurance when applicable. Such insurance will not be construed to create a limit of a Party's liability with respect to its indemnification obligations under this Article 10. Each Party will provide the other Party with written evidence of such insurance. Notwithstanding any provision to the contrary set forth in this Agreement, Alnylam may self-insure, in whole or in part, the insurance requirements described above.

11. INTELLECTUAL PROPERTY.

11.1 **Inventorship**. Inventorship for inventions and discoveries conceived or reduced to practice during the course of the performance of activities pursuant to this Agreement will be determined in accordance with United States patent laws for determining inventorship.

11.2 **Ownership and Disclosure**.

11.2.1Each Party will at all times Control all intellectual property Controlled by such Party prior to the Effective Date or developed or acquired independently of the Agreement.

11.2.2Except as set forth in Section 11.2.3, ownership of all inventions and discoveries (and Patent Rights claiming patentable inventions therein) first conceived or reduced to practice or, with respect to inventions and discoveries other than patentable inventions, otherwise identified, developed, made or discovered, by employees or consultants of a Party in the course of conducting activities under this Agreement will be based on inventorship, as determined in accordance with Section 11.1.

11.2.3As between the Parties, (a) Alnylam will own all Alnylam Collaboration Know-How and all Alnylam Collaboration Patents and (b) Tenaya will own all Tenaya Collaboration Know-How, Tenaya Collaboration Patents, and Tenaya Platform Technology, including any Tenaya Platform Improvement.

11.2.4The Parties shall jointly own the Joint Collaboration Technology.

11.2.5On the Collaboration Target List Finalization Date, Tenaya shall provide complete copies of all Tenaya Collaboration Patents (including any unpublished provisional or other Patent Right) owned or Controlled by Tenaya or any of its Affiliates as of the Collaboration Target List Finalization Date that are necessary or reasonably useful to perform the Tenaya Research Activities and to Exploit any Licensed Product Directed To a Collaboration Target. In addition, (a) Alnylam will promptly disclose to Tenaya all Know-How within the Joint Collaboration Technology ("**Joint Collaboration Know-How**") and Tenaya Platform Improvements, and (b) Tenaya will promptly disclose to Alnylam all Joint Collaboration Know-How and Alnylam Collaboration Know-How, in each case ((a) and (b)) that is developed or invented during the Term by or on behalf of such Party in the course of activities conducted pursuant to this Agreement.

11.3 **Assignment**.

11.3.1Each Party hereby assigns (and, to the extent such present assignment is not possible, agrees to assign) to the other Party all Patent Rights and Know-How as necessary to achieve ownership as provided in Section 11.2. Each assigning Party will execute and deliver all documents and instruments reasonably requested by the other Party to evidence or record such assignment or to file for, perfect or enforce the assigned rights. Each assigning Party hereby appoints the other Party as attorney-in-fact solely to execute and deliver the foregoing documents and instruments if such other Party after making reasonable inquiry does not obtain them from the assigning Party. Each Party will perform its activities under this Agreement through personnel who have made a similar assignment and appointment to and of such Party. Each assigning Party will make its relevant personnel (and their assignments and signatures on such documents and instruments) reasonably available to the other Party for assistance in accordance with this Section 11.3 at no charge.

11.3.2Each Party will cause all Persons who perform activities for such Party under this Agreement to be under an obligation to assign their rights in any Know-How and inventions resulting therefrom to such Party, except (a) if Applicable Law requires otherwise, (b), in the case of governmental, not-for-profit and public institutions which have standard policies against such an assignment, or (c) in the case of any Third Party services provider (such as a contract manufacturer or contract research organization), with respect to any Know-How or inventions that constitute improvements to the background intellectual property of such Third Party, in which case ((a) through (c)), such Party will use commercially reasonable efforts to obtain a suitable license, or right to obtain such a license, with respect to such Know-How and inventions, it being understood and agreed that in the case of Third Party service providers it may be commercially reasonable not to obtain a license.

11.4 **Prosecution, Maintenance and Enforcement of Patent Rights**.

11.4.1**By Tenaya**. Tenaya has the sole right (but not the obligation) to, at Tenaya's discretion, file, conduct prosecution, maintain (including the defense of any interference, opposition or any other pre- or post-grant proceedings or challenges) and enforce, all Tenaya Platform Patents, in Tenaya's name.

11.4.2**By Alnylam**.

(a) **Alnylam Patents**. Alnylam has the sole right (but not the obligation) to, at Alnylam's discretion, file, conduct prosecution, maintain (including the defense of any interference, opposition or any other pre- or post-grant proceedings or challenges) and enforce, all Alnylam Patents, in Alnylam's name.

(b) **Tenaya Collaboration Patents**.

(i) During the Term, Alnylam has the [***] right (but not the obligation) to file, conduct prosecution, and maintain (including the defense of any interference, opposition or any other pre- or post-grant proceedings or challenges), all Tenaya Collaboration Patents, in Tenaya's name. Alnylam will (A) provide Tenaya with copies of all material communications to and from any patent authority regarding such Tenaya Collaboration Patents, including without limitation office actions, responses, and notices of allowance, in a timely manner; (B) consult with Tenaya and provide Tenaya with a reasonable opportunity to review and comment on Alnylam's prosecution strategy for such Tenaya Collaboration Patents, including without limitation the countries in which applications will be filed, the scope of claims to be pursued, responses to office actions, and any decisions to abandon, disclaim, or narrow claims; and (C) consider in good faith all comments provided by Tenaya regarding prosecution strategy..

(ii) Alnylam has the [***] right (but not the obligation) to enforce all Tenaya Collaboration Patents against any infringement by a Third Party in connection with such Third Party's Exploitation of a product that would have been a Product if

developed under this Agreement ("**Infringement**"). Alnylam shall keep Tenaya regularly informed of the status and progress of such enforcement efforts, including providing Tenaya a reasonable opportunity to comment on Alnylam's determination of litigation strategy and the filing of important papers to the competent court and Alnylam shall consider such comments in good faith. Tenaya shall have the right, at its own expense, to retain its own counsel with respect to its participation in any such action.

(iii) [***].

(c) **Joint Collaboration Patents**.

(i) During the Term, Alnylam has the [***] right to file, prosecute, and maintain (including the defense of any interference, opposition or any other pre- or post-grant proceedings or challenges), all Patent Rights comprising Joint Collaboration Technology ("**Joint Collaboration Patents**"), in both Parties' names. Alnylam will (A) provide Tenaya with copies of all material communications to and from any patent authority regarding such Joint Collaboration Patents, including without limitation office actions, responses, and notices of allowance, in a timely manner; (B) consult with Tenaya and provide Tenaya with a reasonable opportunity to review and comment on Alnylam's prosecution strategy for such Joint Collaboration Patents, including without limitation the countries in which applications will be filed, the scope of claims to be pursued, responses to office actions, and any decisions to abandon, disclaim, or narrow claims; and (C) consider in good faith all comments provided by Tenaya regarding prosecution strategy. [***].

(ii) Alnylam has the [***] right (but not the obligation) to enforce all Joint Collaboration Patents against any Infringement. [***].

11.4.3**Cooperation**. At the reasonable request of the Party responsible for prosecution, maintenance, enforcement or defense under this Section 11.4, the other Party agrees to cooperate fully in the preparation, filing, prosecution, enforcement, defense and maintenance (including conducting or participating in inter partes reviews, post grant reviews, derivation proceedings, interferences and oppositions and the like) of any Patent Rights under this Agreement. Such cooperation includes executing all papers and instruments (or causing its personnel to do so) reasonably useful to enable the other Party to apply for and to prosecute patent applications in any country; and promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution, enforcement, defense or maintenance of any such Patent Rights.

11.4.4**Patent Expenses**. The patent filing, prosecution and maintenance expenses incurred after the Effective Date with respect to (a) the Alnylam Patents, will be borne by [***], (b) the Tenaya Collaboration Patents, will be borne by [***], (c) the Tenaya Platform Patents, will be borne by [***], and (d) the Joint Collaboration Patents, will be borne [***]

11.4.5**Procedures; Expenses and Recoveries**. The Party having the right to initiate any infringement suit under this Section 11.4 will have the sole and exclusive right to select counsel for any such suit and will pay all expenses of the suit, including attorneys' fees and court costs and

reimbursement of the other Party's reasonable costs and expenses in rendering assistance requested by the initiating Party. If required under Applicable Law in order for the initiating Party to initiate and/or maintain such suit, or if either Party is unable to initiate or prosecute such suit solely in its own name or it is otherwise advisable to obtain an effective legal remedy, in each case, the other Party will join as a party to the suit and will execute and cause its Affiliates to execute all documents, and take all actions, reasonably necessary for the initiating Party to initiate litigation and maintain such action. In addition, at the initiating Party's request, the other Party will provide other reasonable assistance to the initiating Party in connection with an infringement suit at no charge to the initiating Party except for reimbursement by the initiating Party of reasonable costs and expenses incurred in rendering such assistance. The non-initiating Party will have the right to participate and be represented in any such suit under this Section 11.4 by its own counsel at its own expense. If the Parties obtain from a Third Party, in connection with any such suit under this Section 11.4, any damages, license fees, royalties or other compensation (including any amount received in settlement of such litigation), such amounts will be allocated in all cases as follows: (a) first, to reimburse each Party for all costs and expenses of the suit incurred by the Parties, including attorneys' fees and disbursements, court costs and other litigation expenses and, to the extent that such recovery is insufficient to fully reimburse each Party, each Party will be reimbursed pro rata in accordance with each Party's costs and expenses; and (b) second, the balance will be paid as follows: (ii) if Tenaya is the initiating Party, [***]; and (ii) if Alnylam is the initiating Party, [***].

11.5 **Exploitation of Joint Collaboration Technology**. Subject to the exclusive license granted to Alnylam in Section 6.2, Tenaya's exclusivity obligation in Section 6.6, and the rights set forth in Section 11.4, each Party (a) will own an equal and undivided interest in the Joint Collaboration Technology and (b) may freely Exploit for any and all purposes, either by itself or through the grant of licenses to Third Parties, any Joint Collaboration Technology on a cost-free basis and with no accounting or obligation to the other Party. Each Party will grant and hereby does grant to the other Party all further permissions, consents, and waivers with respect to, and all licenses under, any Joint Collaboration Technology throughout the world necessary to provide the other Party with full rights of use and Exploitation of such Joint Collaboration Technology.

11.6 **CREATE Act**. It is the Parties' intention that this Agreement is a "joint research agreement" as that phrase is defined in 35 U.S.C. § 102(c) as amended by the Cooperative Research and Technology Enhancement (CREATE) Act, including the provisions of 35 U.S.C. § 102(b)(2)(c). The Parties agree to cooperate and to take reasonable actions to maximize the protections available for the Products under such safe harbor provisions.

11.7 **Common Interest Agreement**. All non-public information exchanged between the Parties or between a Party's outside patent counsel and the other Party regarding the preparation, filing, prosecution, maintenance, defense and enforcement of the Tenaya Collaboration Patents (or counterparts thereto), Joint Collaboration Patents, or otherwise related to any Product, and all shared information regarding analyses or opinions of Third Party Patent Rights or Know-How, shall be deemed Confidential Information. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning any such Patent Rights, Know-How or Confidential Information, including privilege under the common interest doctrine and similar or related doctrines. In furtherance of the foregoing, if the Parties agree that a separate agreement memorializing this understanding would be advantageous, the Parties shall negotiate and enter into a common interest agreement reflecting this understanding or any other common interest agreement as the Parties may mutually agree, including with respect to any product liability for a Product.

12. **TERM AND TERMINATION**.

12.1 **Term**. The Agreement would commence on the Effective Date and would expire (a) on a Non-Alnylam Collaboration Target-by-Non-Alnylam Collaboration Target basis (i) in the event that Alnylam does not commence an NHP PD Study of a Product Directed To such Non-Alnylam Collaboration Target, upon the expiration of the Evaluation Term for such Non-Alnylam Collaboration Target or when such Non-Alnylam Collaboration Target otherwise ceases to be a Collaboration Target, or (ii) in the event that Alnylam does commence an NHP PD Study of a Product Directed To such Non-Alnylam Collaboration Target prior to the expiration of the Evaluation Term for such Non-Alnylam Collaboration Target, the date on which no more payments remain payable hereunder with respect to such Non-Alnylam Collaboration Target, or (b) on an Alnylam Gene Target-by-Alnylam Gene Target basis upon the completion of *In Vitro* Validation Activities and *In Vivo* Validation Activities under the Research Plan with respect thereto (the "**Term**"). Upon expiration under the foregoing subsections (a)(ii) and (b), Alnylam would have a perpetual, exclusive, royalty-free license (with the right to sublicense) under the Licensed Technology to discover, research, Develop, manufacture, Commercialize and otherwise Exploit Products Directed To the applicable Collaboration Target.

12.2 **Termination Rights**.

12.2.1**Termination for Convenience**. Alnylam will have the right to terminate this Agreement in its entirety, or with respect to any Collaboration Target, at any time after the Effective Date upon [***] prior written notice to Tenaya; provided that Alnylam's payment obligations under Sections 7.2 and 7.3 with respect to any Non-Alnylam Collaboration Target shall survive such termination if Alnylam continues to exploit any Licensed Product Directed To such Non-Alnylam Collaboration Target, if such termination occurs after Tenaya's delivery of the *In Vitro* Data Package for such Non-Alnylam Collaboration Target.

12.2.2**Termination for Cause**. This Agreement may be terminated at any time during the Term upon written notice by either Party (the "**Non-Breaching Party**") if the other Party (the "**Breaching Party**") is in material breach of its obligations hereunder and has not cured such breach within [***] in the case of a payment breach, or within [***] in the case of all other breaches, after notice requesting cure of the breach, or, if cure of such breach other than non-payment cannot reasonably be effected within such [***] period, has not delivered to the Non-Breaching Party a plan reasonably calculated to cure such breach within a timeframe that is reasonably prompt in light of the circumstances then prevailing, but in no event more than [***]. Following delivery of such a plan, the Breaching Party will carry out the plan and cure the breach. If the Breaching Party fails to cure a material breach of this Agreement as provided above, then the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party, provided that if Tenaya is the Non-Breaching Party, then Tenaya may terminate this Agreement solely with respect to the Product to which the uncured breach relates. Notwithstanding the foregoing, if the Breaching Party in this Section 12.2.2 disputes in good faith the existence, materiality, or failure to cure of any breach, and provides written notice to the Non-Breaching Party of such dispute within the relevant cure period, the Non-Breaching Party will not have the right to terminate this Agreement in accordance with Section 12.2.2 unless and until the relevant dispute has been resolved pursuant to the dispute resolution provisions in Section 13.12. During the pendency of such dispute, all the terms of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.

12.2.3**Termination for Insolvency**. If, at any time during the Term, either Party makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within [***] after the filing thereof, the other Party may terminate this Agreement in its entirety by providing written notice of its intent to terminate this Agreement to such Party, in which case, this Agreement will terminate on the date on which such Party receives such written notice.

12.3 **Certain Additional Remedies in Lieu of Termination**. In the event that (a) Alnylam notifies Tenaya in writing of a material breach of [***] by Tenaya, and (b) following a final resolution of any Dispute related to such material breach, or its cure, in accordance with Section 12.2.2, Alnylam would have the right to terminate this Agreement pursuant to Section 12.2.2, then in lieu of Alnylam terminating pursuant to Section 12.2.2 (including following expiration of any applicable cure periods), Alnylam may, as its sole remedy for such breach, elect to have this Agreement continue in full force and effect by providing written notice thereof to Tenaya; provided, however, that if Alnylam so elects to continue this Agreement, then from and after such time as Alnylam delivers such written notice to Tenaya, any and all amounts thereafter payable by Alnylam thereafter under Sections 7.2 and 7.3, solely with respect to the Non-Alnylam Collaboration Target to which the uncured material breach relates, will be reduced by [***].

12.4 **Effect of Termination**. If this Agreement is terminated in its entirety or with respect to one or more Non-Alnylam Collaboration Targets, the following terms will apply to this Agreement, either in its entirety or, on a Terminated Collaboration Target-by-Terminated Collaboration Target basis, with respect to the Terminated Collaboration Targets(s) that are the subject of such termination, as the case may be:

12.4.1**Cessation of Rights**. All rights and licenses granted by either Party to the other Party and all obligations under this Agreement will terminate (provided that the licenses will continue on a non-exclusive basis solely for purposes of completing wind-down activities).

12.4.2**Return of Confidential Information**. Subject to Section 8.1.1, upon the expiration or termination of this Agreement, the Receiving Party will return to the Disclosing Party or, as directed by the Disclosing Party, destroy (and certify such destruction in writing) all Confidential Information of the Disclosing Party (or if the Agreement is terminated with respect to one or more Collaboration Targets but not in its entirety, all Confidential Information of the Disclosing Party that solely relates to such Terminated Collaboration Target), that is in the Receiving Party's or its Affiliates' or Sublicensees' possession or control, provided, however, that copies may be retained and stored by the Receiving Party solely for the purpose of determining its obligations under this Agreement, subject to the non-disclosure and non-use obligation under Article 8. In addition, the Receiving Party will not be required to return or destroy Confidential Information contained in any computer system back-up records made in the ordinary course of business; provided that such Confidential Information may not be accessed without the Disclosing Party's prior written consent or as required by Applicable Law.

12.4.3[***]

12.5 **Effect of Expiration or Termination; Survival**. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination of this Agreement will be without prejudice to the rights of either Party against the other accrued

or accruing under this Agreement prior to expiration or termination. The provisions of Sections 2.5 (to the extent reimbursement obligations are incurred prior to the effective date of termination or expiration), 2.9, 6.4, 7.2 (to the extent payment obligations are incurred prior to the effective date of termination or expiration), 7.3 (to the extent payment obligations are incurred prior to the effective date of termination or expiration), 7.4, 7.5, 7.6, 7.7, 7.8, 9.5, 11.1, 11.2, 11.3, 11.5, 11.7 12.4, and 12.5 and Articles 1, 8, 10 and 13 will survive any expiration or termination of this Agreement. Except as set forth in this Article 12, upon termination or expiration of this Agreement all other rights and obligations of the Parties under this Agreement cease.

13. **MISCELLANEOUS**.

13.1 **Assignment**. Except as provided in this Section 13.1, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the written consent of the other Party. However, either Party may, without the other Party's written consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate or to a Person that acquires, by merger, sale of assets or otherwise, all or substantially all of the business of the assigning Party to which the subject matter of this Agreement relates. The assigning Party will remain responsible for the performance by its assignee of this Agreement or any obligations hereunder so assigned. Any assignment of the rights or obligations of this Agreement not in accordance with the foregoing will be null and void.

13.2 **Governing Law**. This Agreement will be construed and the respective rights of the Parties determined in accordance with the substantive laws of the State of New York, notwithstanding any provisions of New York law governing conflicts of laws to the contrary, and the patent laws of the relevant jurisdiction without reference to any rules of conflict of laws.

13.3 **Entire Agreement; Amendments**. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof, and supersedes all previous arrangements with respect to the subject matter hereof, whether written or oral, including term sheets exchanged between the Parties and the Confidentiality Agreement. This Agreement (including the Exhibits and Schedules hereto) may be amended, or any term hereof modified, only by a written instrument duly-executed by authorized representatives of both Parties.

13.4 **Severability**. If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties will substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalid, illegal or unenforceable of one or several provisions of this Agreement will not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid, illegal or unenforceable provisions.

13.5 **Headings**. The captions to the Sections and Articles hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Sections and Articles hereof.

13.6 **Interpretation**. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms and any noun will include the corresponding singular and plural

forms. The words "include", "includes" and "including" will be deemed to be followed by the phrase "but not limited to." The word "shall" will be construed to have the same meaning and effect as the word "will. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any laws herein will be construed as referring to such laws as from time to time enacted, repealed or amended, (c) any reference herein to any Person will be construed to include the Person's successors and permitted assigns, (d) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) all references herein to Sections, Articles, Exhibits or Schedules will be construed to refer to Sections, Articles, Exhibits and Schedules of this Agreement, (f) the word "or" will be construed to have the same meaning and effect as "and/or", and (g) a term not defined herein but reflecting a different part of speech than a term which is defined herein will be interpreted in a correlative manner.

13.7 **Construction**. This Agreement has been prepared jointly and will not be strictly construed against either Party. Ambiguities, if any, in this Agreement will not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

13.8 **No Implied Waivers; Rights Cumulative**. No failure on the part of Alnylam or Tenaya to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor will any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege. Except as expressly provided in this Agreement, no right or remedy herein conferred upon or reserved to either Party is intended to be exclusive of any other right or remedy.

13.9 **Notices**. All notices which are required or permitted hereunder will be in writing and sufficient if (a) delivered personally, (b) sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, or (c) sent by electronic transmission (and a copy promptly sent by another permissible method of providing notice described in paragraph (a) or (b) above), addressed as follows:

If to Alnylam, to: Alnylam Pharmaceuticals, Inc.
675 West Kendall Street Henri A. Termeer Square
Cambridge, MA 02142 United States
Attention: [***]
Email: [***]

If to Tenaya, to: Tenaya Therapeutics, Inc.
171 Oyster Point Blvd., Suite 500
Attention: [***]
Email: [***]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) when delivered if personally delivered on a Business Day (or if delivered on a non-Business Day, then on the next Business Day); (b) on receipt if sent by overnight courier or registered or certified mail; and/or (c) with regard to notices sent by email, as recorded on the device from which the sender sent the email unless the sender receives an automated message that the email has not been delivered.

13.10 **Compliance with Export Regulations**. Neither Party will export any technology licensed to it by the other Party under this Agreement except in compliance with Applicable Law.

13.11 **Force Majeure**. Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, epidemic or pandemic (excluding the COVID-19 pandemic); or other acts of God, or acts, omissions or delays in acting by any Governmental Authority or the other Party. The affected Party will notify the other Party of such force majeure circumstances as soon as reasonably practical, and will promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

13.12 **Dispute Resolution**. In the event that the Parties do not resolve any dispute, controversy or claim arising from, or related to, this Agreement or to the breach hereof (collectively, "**Dispute**"), either Party may refer the Dispute to Executive Officers of each Party for resolution within [***] of a written request by either Party to the other Party. Each Party, within [***] after a Party has received such written request from the other Party to so refer such Dispute, shall notify the other Party in writing of the Executive Officer to whom such Dispute is referred. If, after an additional [***] after the notice of Dispute, such Executive Officers have not succeeded in negotiating a resolution of the Dispute, and neither Party has final decision-making authority as to such Dispute pursuant to Section 5.3, and a Party wishes to pursue the matter, each such Dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce (or its successor entity). Judgment on the arbitration award may be entered in any court of competent jurisdiction thereof. The arbitration shall be decided by a tribunal of three (3) arbitrators, irrespective of the amount in controversy. Each Party shall nominate one arbitrator, and the third, who shall act as presiding arbitrator, shall be nominated by the two (2) Party-nominated arbitrators within [***] of the second arbitrator's appointment. The seat, or legal place of arbitration, shall be New York, New York, U.S. Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award any damages proscribed by Section 11.4 hereof. The prevailing Party shall be awarded all costs and attorneys' fees reasonably incurred in the arbitration and in the enforcement or vacatur of any award. Except to the extent necessary to confirm, vacate, or enforce an award, or as may be required by Applicable Law, or as needed for the preparation or presentation of claim or defense in the arbitration, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the Dispute would be barred by the applicable statute of limitations. The tribunal may render early or summary disposition of some or all issues, after the Parties have had a reasonable opportunity to make submissions on these issues.

13.13 **Independent Contractors**. It is expressly agreed that Alnylam and Tenaya will be independent contractors and that the relationship between Alnylam and Tenaya will not constitute a partnership, joint venture or agency. Alnylam will not have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on Tenaya, without the prior written consent of Tenaya, and Tenaya will not have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on Alnylam, without the prior written consent of Alnylam. For clarity, the Parties' activities under the Research Plan constitute a research collaboration and neither Party shall be deemed a services provider of the other Party.

13.14 **Counterparts**. The Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Signatures transmitted via PDF will be treated as original signatures.

13.15 **Performance by Affiliates**. Each Party will have the right to have any of its obligations hereunder performed by any of its Affiliates and the performance of such obligations by any such Affiliate(s) will be deemed to be performance by such Party; provided, however, that such Affiliate will be bound by the corresponding obligations of such Party and such Party will be responsible for ensuring the performance of its obligations under this Agreement and that any failure of any Affiliate performing obligations of such Party hereunder will be deemed to be a failure by such Party to perform such obligations.

13.16 **Binding Effect; No Third Party Beneficiaries**. As of the Effective Date, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Except as expressly set forth in this Agreement, no person or entity other than the Parties and their respective permitted assignees hereunder will be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

[*Signature Page Follows*]

IN WITNESS WHEREOF, an authorized representative of each Party has executed this Agreement as of the Effective Date.

TENAYA THERAPEUTICS, INC.	**ALNYLAM PHARMACEUTICALS, INC.**
/s/ Faraz Ali	/s/ Jeff Poulton
Name: Faraz Ali	Name: Jeff Poulton
Title: Chief Executive Officer	Title: CFO
Date: 04-Mar-2026	Date: 04-Mar-2026

Exhibit A
Research Plan and Research Budget

[***]

Schedule 1.104
Tenaya Nominated Gene Targets

[***]

Schedule 5.1
JSC Members as of the Effective Date

[***]

Schedule 8.2.2
Tenaya Press Release

Tenaya Therapeutics Enters into Research Collaboration with Alnylam Pharmaceuticals to Identify and Validate Novel Genetic Targets for Cardiovascular Disease Therapeutics

Agreement Combines Tenaya's Expertise in Identification and Validation of Genetic Heart Disease Targets with Alnylam's Ability to Deliver Transformational Therapeutics

Tenaya to Receive Up to $10 Million in Upfront Payments in Addition to Research Funding and Milestone Payments of Up to $1.13 Billion

South San Francisco, CA, Calif., [DATE, 2026] – Tenaya Therapeutics, Inc. (NASDAQ: TNYA), a clinical-stage biotechnology company with a mission to discover, develop and deliver potentially curative therapies that address the underlying causes of heart disease, today announced a research collaboration agreement with Alnylam Pharmaceuticals (Nasdaq: ALNY), the leading RNAi therapeutics company, to discover novel human genetic targets for the potential development of disease-modifying treatments for cardiovascular diseases.

"This multi-target collaboration underscores Tenaya's commitment to rigorous science and capitalizes on the proprietary capabilities that have contributed to the discovery and development of Tenaya's pipeline of candidates for cardiovascular conditions," said Faraz Ali, Chief Executive Officer of Tenaya Therapeutics. "By combining our modality agnostic target identification and validation capabilities with Alnylam's leadership in RNA interference therapeutics, we have an opportunity to advance candidates for novel genetic targets with the potential to create transformational medicines for patients with heart disease."

Under the terms of the agreement, Tenaya Therapeutics will validate up to 15 gene targets. Tenaya will receive up to $10 million in the form of an upfront payment, in addition to reimbursement for related costs incurred over the two-year validation term. Alnylam will be responsible for all development and commercialization activities of therapeutics associated with the identified gene targets. Tenaya may be eligible to receive as much as $1.13 billion in development and commercial milestone payments from Alnylam should all novel genetic targets lead to approved therapeutics for cardiovascular disease.

About Tenaya's Target Identification and Validation Capabilities
Tenaya has established a diverse portfolio of proprietary integrated capabilities to enable modality agnostic target identification and validation anchored in human genetics. These capabilities encompass the use of human induced pluripotent stem cell-derived cardiomyocytes (iPSC-CMs) with high throughput *in vitro* screening, imaging analysis and machine learning algorithms to identify novel genetic targets, and human engineered heart tissue and preclinical *in vivo* models of human disease to validate and characterize potential product candidates. Collectively, Tenaya's target identification and validation capabilities have generated more than 150 genetic targets and contributed to the discovery and development of the company's clinical-stage candidates, including the TN-201 and TN-401 gene therapies and TN-301 small molecule, as well as diverse early-stage programs.

About Tenaya Therapeutics
Tenaya Therapeutics is a clinical-stage biotechnology company committed to a bold mission: to discover, develop and deliver potentially curative therapies that address the underlying drivers of heart disease. Tenaya's pipeline includes clinical-stage candidates TN-201, a gene therapy for *MYBPC3*-associated hypertrophic cardiomyopathy (HCM) and TN-401, a gene therapy for *PKP2*-associated arrhythmogenic right ventricular cardiomyopathy (ARVC). Tenaya has employed a suite of integrated internal capabilities, including modality agnostic target validation, capsid engineering and manufacturing, to generate a portfolio of novel medicines based on genetic insights, including TN-301, a clinical-stage small molecule HDAC6 inhibitor for the potential treatment of heart failure and related cardio/muscular disease, and multiple early-stage programs in preclinical development aimed at the treatment of both rare genetic disorders and more prevalent heart conditions. For more information, visit www.tenayatherapeutics.com.

Forward Looking Statements
This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Words such as "commitment," "opportunity," "potential," "will," and "may," and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, Tenaya's commitment to rigorous science; the opportunity to advance candidates for novel genetic targets and potential to create transformational medicines for patients with heart disease under the collaboration; the potential for Tenaya to receive upfront, development and commercial milestone payments, as well as research reimbursement under the collaboration; and statements made by Tenaya's Chief Executive Officer. The forward-looking statements contained herein are based upon Tenaya's current expectations and involve assumptions that may never materialize or may prove to be incorrect. These forward-looking statements are neither promises nor guarantees and are subject to a variety of risks and uncertainties, including but not limited to: Tenaya's ability to achieve the expected benefits from the collaboration; risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics; Tenaya's continuing compliance with applicable legal and regulatory requirements; Tenaya's ability to raise any additional funding it will need to continue to execute on its business plans, including performing its obligations under the collaboration with Alnylam; unanticipated early termination of the collaboration with Alnylam; Tenaya's reliance on third parties; Tenaya's research capabilities and strategy; the loss of key scientific or management personnel; Tenaya's ability to obtain and maintain intellectual property protection for its platform technology and product candidates; general economic and market conditions; and other risks. Information regarding the foregoing and additional risks may be found in the section titled "Risk Factors" in Tenaya's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2025, and other documents that Tenaya files from time to time with the Securities and Exchange Commission. These forward-looking statements are made as of the date of this press release, and Tenaya assumes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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Exhibit 31.1

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

I, Faraz Ali, M.B.A., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tenaya 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. I have disclosed, based on my 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 6, 2026

TENAYA THERAPEUTICS, INC.

By: /s/ Faraz Ali, M.B.A.
Name: Faraz Ali, M.B.A.
Title: Chief Executive Officer and Director
(Principal Executive Officer and Interim Principal Financial Officer)

Exhibit 32.1

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

I, Faraz Ali, M.B.A., certify, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, (1) the Quarterly Report on Form 10-Q of Tenaya Therapeutics, Inc. (the "Company") for the quarterly period ended March 31, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Faraz Ali, M.B.A.
Faraz Ali, M.B.A.
Chief Executive Officer and Director
(Principal Executive Officer and Interim Principal Financial Officer)

Date: May 6, 2026