

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 September 30, 2024  
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  
(State or other jurisdiction of  
incorporation or organization)  
171 Oyster Point Boulevard, Suite 500  
South San Francisco, CA  
(Address of principal executive offices)

81-3789973  
(I.R.S. Employer  
Identification No.)  
94080  
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of October 31, 2024, the registrant had 79,220,516 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, or Quarterly Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Act of 1934. 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 and approvals, 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 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;
- 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 investor's 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)*

	September 30, 2024	December 31, 2023
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,231	\$ 45,681
Short-term investments in marketable securities	71,238	58,961
Prepaid expenses and other current assets	5,861	6,940
Total current assets	85,330	111,582
Property and equipment, net	37,753	43,277
Operating lease right-of-use assets	12,626	9,979
Other noncurrent assets	4,873	5,677
Total assets	<u>\$ 140,582</u>	<u>\$ 170,515</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,839	\$ 5,630
Accrued and other current liabilities	7,327	12,784
Operating lease liabilities, current	3,011	4,319
Total current liabilities	16,177	22,733
Operating lease liabilities, noncurrent	11,527	8,105
Other noncurrent liabilities	276	253
Total liabilities	27,980	31,091
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Common stock	8	7
Additional paid-in capital	603,093	542,805
Accumulated other comprehensive loss	76	(106)
Accumulated deficit	(490,575)	(403,282)
Total stockholders' equity	112,602	139,424
Total liabilities and stockholders' equity	<u>\$ 140,582</u>	<u>\$ 170,515</u>

*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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 20,350	\$ 23,091	\$ 68,054	\$ 75,173
General and administrative	6,361	7,829	23,242	24,574
Total operating expenses	26,711	30,920	91,296	99,747
Loss from operations	(26,711)	(30,920)	(91,296)	(99,747)
Other income, net:				
Interest income	1,080	1,776	3,925	5,586
Other income (loss), net	(3)	1	78	12
Total other income, net	1,077	1,777	4,003	5,598
Net loss before income tax expense	(25,634)	(29,143)	(87,293)	(94,149)
Income tax expense	—	—	—	—
Net loss	(25,634)	(29,143)	(87,293)	(94,149)
Other comprehensive income (loss):				
Net unrealized gain on marketable securities	143	72	182	117
Comprehensive loss	<u>\$ (25,491)</u>	<u>\$ (29,071)</u>	<u>\$ (87,111)</u>	<u>\$ (94,032)</u>
Net loss per share, basic and diluted	<u>\$ (0.30)</u>	<u>\$ (0.39)</u>	<u>\$ (1.04)</u>	<u>\$ (1.28)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>86,162,841</u>	<u>73,924,937</u>	<u>84,290,747</u>	<u>73,579,200</u>

*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 Shares	Common Stock Amount		Additional Paid-In Capital	Accumulated Other Comprehensiv e Loss	Accumulated Deficit	Total Stockholders' Equity
Balance as of January 1, 2024	68,330,342	\$ 7	\$	542,805	\$ (106)	\$ (403,282)	\$ 139,424
Issuance of common stock and pre-funded warrants, net of issuance costs of \$3,236	8,888,890			46,761			46,762
Issuance of common stock upon exercise of stock options and vesting of restricted stock units	246,708	—		11	—	—	11
Issuance of common stock upon exercise of pre-funded warrants	1,051,594	—		1	—	—	1
Stock-based compensation	—	—		4,224	—	—	4,224
Other comprehensive loss	—	—		—	(14)	—	(14)
Net loss	—	—		—	—	(32,228)	(32,228)
Balance as of March 31, 2024	<u>78,517,534</u>	<u>\$ 8</u>	<u>\$</u>	<u>593,802</u>	<u>\$ (120)</u>	<u>\$ (435,510)</u>	<u>\$ 158,180</u>
Issuance of common stock pursuant to employee stock purchase plan	320,951	—		554	—	—	554
Issuance of common stock upon exercise of stock options and vesting of restricted stock units	28,952	—		30	—	—	30
Stock-based compensation	—	—		4,611	—	—	4,611
Other comprehensive income	—	—		—	53	—	53
Net loss	—	—		—	—	(29,431)	(29,431)
Balance as of June 30, 2024	<u>78,867,437</u>	<u>\$ 8</u>	<u>\$</u>	<u>598,997</u>	<u>\$ (67)</u>	<u>\$ (464,941)</u>	<u>\$ 133,997</u>
Issuance of common stock upon exercise of stock options and vesting of restricted stock units	353,079	—		14	—	—	14
Issuance of warrant	—	—		175	—	—	175
Stock-based compensation	—	—		3,907	—	—	3,907
Other comprehensive income	—	—		—	143	—	143
Net loss	—	—		—	—	(25,634)	(25,634)
Balance as of September 30, 2024	<u>79,220,516</u>	<u>\$ 8</u>	<u>\$</u>	<u>603,093</u>	<u>\$ 76</u>	<u>\$ (490,575)</u>	<u>\$ 112,602</u>

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensiv e Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of January 1, 2023	66,857,113	\$ 7	\$ 522,945	\$ (378)	\$ (279,198)	\$ 243,376
Issuance of common stock upon exercise of stock options and vesting of restricted stock units	8,311	—	—	—	—	—
Vesting of early exercised stock options	—	—	1	—	—	1
Stock-based compensation	—	—	3,514	—	—	3,514
Other comprehensive income	—	—	—	258	—	258
Net loss	—	—	—	—	(31,737)	(31,737)
Balance as of March 31, 2023	<u>66,865,424</u>	<u>\$ 7</u>	<u>\$ 526,460</u>	<u>\$ (120)</u>	<u>\$ (310,935)</u>	<u>\$ 215,412</u>
Issuance of common stock in connection with at-the-market sales, net of issuance costs of \$120	535,767	—	3,868	—	—	3,868
Issuance of common stock upon exercise of pre-funded warrants	302,517	—	—	—	—	—
Issuance of common stock pursuant to employee stock purchase plan	150,575	—	282	—	—	282
Issuance of common stock upon exercise of stock options	10,875	—	29	—	—	29
Stock-based compensation	—	—	3,831	—	—	3,831
Other comprehensive loss	—	—	—	(213)	—	(213)
Net loss	—	—	—	—	(33,269)	(33,269)
Balance as of June 30, 2023	<u>67,865,158</u>	<u>\$ 7</u>	<u>\$ 534,470</u>	<u>\$ (333)</u>	<u>\$ (344,204)</u>	<u>\$ 189,940</u>
Issuance of common stock upon vesting of restricted stock units	245,861	—	—	—	—	—
Stock-based compensation	—	—	4,015	—	—	4,015
Other comprehensive income	—	—	—	72	—	72
Net loss	—	—	—	—	(29,143)	(29,143)
Balance as of September 30, 2023	<u>68,111,019</u>	<u>\$ 7</u>	<u>\$ 538,485</u>	<u>\$ (261)</u>	<u>\$ (373,347)</u>	<u>\$ 164,884</u>

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



**TENAYA THERAPEUTICS, INC.**

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

	Nine Months Ended September 30,	
	2024	2023
<b>Cash flows from operating activities:</b>		
Net loss	\$ (87,293 )	\$ (94,149 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6,379	6,506
Amortization (accretion) of premium (discount) on marketable securities	56	(1,371 )
Stock-based compensation	12,742	11,360
Non-cash operating lease expense	2,655	2,326
Other	243	157
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,026	2,013
Other noncurrent assets	600	(658 )
Accounts payable	120	(2,977 )
Accrued and other current liabilities	(5,453 )	(300 )
Operating lease liabilities	(3,188 )	(3,055 )
Net cash used in operating activities	(72,113 )	(80,148 )
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(821 )	(845 )
Purchases of marketable securities	(85,058 )	(40,998 )
Proceeds from maturities of marketable securities	72,890	105,484
Other	17	(7 )
Net cash (used in) provided by investing activities	(12,972 )	63,634
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock and pre-funded warrants in follow-on offering, net of issuance costs	46,762	—
Proceeds from exercise of stock options and employee stock purchase plan	609	311
Proceeds from exercises of pre-funded warrants	1	—
Proceeds from at-the-market sales, net of issuance costs	—	3,868
Payment of accrued offering costs	—	(501 )
Net cash provided by financing activities	47,372	3,678
Net change in cash, cash equivalents and restricted cash	(37,713 )	(12,836 )
Cash and cash equivalents and restricted cash at beginning of period	46,363	95,671
Cash and cash equivalents and restricted cash at end of period	<u>\$ 8,650</u>	<u>\$ 82,835</u>
<b>Components of cash, cash equivalents and restricted cash:</b>		
Cash and cash equivalents	\$ 8,231	\$ 82,153
Restricted cash included in other noncurrent assets	419	682
Cash, cash equivalents and restricted cash	<u>\$ 8,650</u>	<u>\$ 82,835</u>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Property and equipment included in accounts payable and accrued and other current liabilities	\$ 334	\$ 309
Issuance of warrant in connection with Loan Agreement	\$ 175	\$ —

*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 for heart failure with preserved ejection fraction.

##### *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 September 30, 2024, the Company had an accumulated deficit of \$490.6 million. The Company incurred a net loss of \$87.3 million and \$94.1 million during the nine months ended September 30, 2024 and 2023, respectively. The Company had \$79.5 million of cash, cash equivalents and investments in marketable securities as of September 30, 2024.

On August 6, 2024, the Company entered into a Loan Agreement with Silicon Valley Bank (SVB), a division of First-Citizens Bank & Trust Company (the Loan Agreement). As of the filing date of this periodic report, under the Loan Agreement, the Company has the right to draw down \$20.0 million at its discretion, up to an additional \$5.0 million upon the satisfaction of certain milestones and up to an additional \$20.0 million that may be available at SVB's discretion, subject to specified conditions. See Note 6, *Term Loan*, for further details.

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, cash equivalents and investments in marketable securities as of September 30, 2024, along with the \$20.0 million of funds available under its Loan Agreement with SVB, will be sufficient to fund the Company's operations for at least the next twelve months following the date these condensed 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 September 30, 2024, the interim condensed statements of operations and comprehensive loss, stockholders' equity and cash flows for the nine months ended September 30, 2024 and 2023 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 nine months ended September 30, 2024, 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, 2023, 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, 2023, included in Company's Annual Report on Form 10-K, filed with the SEC on March 18, 2024.

### 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. 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 to the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

### Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* (ASU 2023-07), which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. In addition, ASU 2023-07 enhances interim disclosure requirements, clarifies circumstances in which an entity can disclose multiple segment measures of profit or loss, provides new segment disclosure requirements for entities with a single reportable segment, and contains other disclosure requirements. ASU 2023-07 is effective for annual periods beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The Company is evaluating the impact of this standard on its financial statements and related disclosures.

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 the Company beginning January 1, 2025. The Company is evaluating the impact of this standard on its financial statements and related disclosures.

## 3. Balance Sheet Components

### Property and Equipment, Net

Property and equipment, net consists of the following:

	September 30, 2024	December 31, 2023
	(In thousands)	
Leasehold improvements	\$ 25,728	\$ 25,608
Laboratory equipment	20,201	19,973
Manufacturing equipment	17,716	17,716
Construction in progress	2,150	1,730
Computer equipment and software	1,664	1,614
Furniture and fixtures	981	976
Total property and equipment	\$ 68,440	\$ 67,617
Less: accumulated depreciation and amortization	(30,687)	(24,340)
Total property and equipment, net	\$ 37,753	\$ 43,277

Depreciation and amortization expense for the three months ended September 30, 2024 and 2023 was \$2.1 million and \$2.2 million, respectively. Depreciation and amortization expense for each of the nine months ended September 30, 2024 and 2023 was \$6.4 million and \$6.5 million, respectively.

**Accrued and Other Current Liabilities**

Accrued and other current liabilities consist of the following:

	September 30, 2024	December 31, 2023
	(In thousands)	
Accrued compensation and related expenses	\$ 4,735	\$ 8,700
Accrued research and development expenses	1,566	2,583
Accrued professional services	389	743
Accrued taxes	202	280
Accrued facility management services	—	185
Other current liabilities	435	293
Total accrued and other current liabilities	<u>\$ 7,327</u>	<u>\$ 12,784</u>

**Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following:

	September 30, 2024	December 31, 2023
	(In thousands)	
Prepaid expenses	\$ 4,458	\$ 5,783
Other current assets	1,403	1,157
Total prepaid expenses and other current assets	<u>\$ 5,861</u>	<u>\$ 6,940</u>

**4. 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.

In November 2021, the Company entered into a sublease agreement for office and laboratory space in South San Francisco, California. The lease was initially set to expire on June 30, 2022. In May 2022, the Company amended the lease to extend the term for the existing sublease premises through December 31, 2022. Pursuant to the terms of the amendment, the Company also subleased additional office and laboratory space at the same subleased premises through November 30, 2023. In October 2023, the Company entered into a second amendment for additional laboratory space and to extend the term of the subleased premises through November 30, 2024.

Information related to operating lease activity during the three and nine months ended September 30, 2024 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(In thousands)			
Operating lease cost	\$ 1,356	\$ 1,090	\$ 3,506	\$ 3,271
Variable lease cost	377	324	1,079	919
Short-term lease cost	—	—	—	5
Total lease cost	<u>\$ 1,733</u>	<u>\$ 1,414</u>	<u>\$ 4,585</u>	<u>\$ 4,195</u>
Operating lease right-of-use assets obtained in exchange for lease obligations			\$ 5,302	\$ —
Cash paid for amounts included in the measurement of lease liabilities			\$ 4,039	\$ 4,000

As of September 30, 2024, the Company's operating leases had a weighted average remaining lease term of 4.9 years and a weighted average discount rate of 8.9%. As of December 31, 2023, the Company's operating leases had a weighted average remaining lease term of 5.1 years and a weighted average discount rate of 9.3%. Future minimum lease payments under the Company's operating leases as of September 30, 2024 were as follows:

	Amount (In thousands)
2024 (remaining 3 months)	\$ 1,238
2025	3,861
2026	3,864
2027	3,775
2028	1,471
Thereafter	4,006
Total undiscounted future minimum lease payments	\$ 18,215
Imputed interest	(3,677)
Total operating lease liabilities	<u>\$ 14,538</u>

#### **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 through the time of termination.

#### **Indemnification**

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 September 30, 2024.

In the normal course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may be obligated to 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 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 September 30, 2024, the Company did not have any material indemnification claims that were probable and consequently has not recorded any related liabilities.

#### **5. 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. As of September 30, 2024, no shares have been issued under the Inducement Plan.

### 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.

Total shares reserved and available for grant under the Inducement Plan and 2021 Plan as of September 30, 2024 are 1,200,000 and 1,355,277, respectively.

### Stock Option Activity

The following table summarizes stock option activity:

	Shares	Weighted-Average Exercise Price (in dollars)
Outstanding as of December 31, 2023	8,343,434	\$ 7.47
Granted	2,470,100	\$ 5.13
Exercised	(32,195)	\$ 1.69
Cancelled	(1,180,558)	\$ 8.21
Outstanding as of September 30, 2024	9,600,781	\$ 6.80

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Expected term (in years)	N/A	6.1	6.0 – 6.1	5.5 – 6.1
Expected volatility	N/A	94%	92% – 93%	94% – 95%
Risk-free interest rate	N/A	4.0% – 4.4%	3.9% – 4.5%	3.4% – 4.4%
Expected dividend yield	N/A	—%	—%	—%

N/A - not applicable as no stock option awards were granted in the period presented.

### 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, 2023	1,088,276	\$	3.34
Granted	1,314,865	\$	4.52
Vested	(596,544)	\$	3.59
Forfeited	(260,806)	\$	4.42
Unvested as of September 30, 2024	<u>1,545,791</u>	\$	4.07

#### 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 September 30, 2024, 1,767,746 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 6 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 nine months ended September 30, 2024 and 2023, 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 2,048	\$ 1,861	\$ 6,283	\$ 5,204
General and administrative	1,859	2,154	6,459	6,156
Total stock-based compensation	<u>\$ 3,907</u>	<u>\$ 4,015</u>	<u>\$ 12,742</u>	<u>\$ 11,360</u>

## 6.Term Loan

#### Loan Agreement

On August 6, 2024, the Company entered into the Loan Agreement with SVB. Pursuant to the terms of the Loan Agreement, term loans in an aggregate principal amount of up to \$45 million may be made under multiple tranches. The tranches can be drawn as follows: the first tranche of up to \$15.0 million became available at the closing date through June 30, 2025; the second tranche of \$5 million became available in October 2024 upon the achievement of a clinical milestone and is available through December 31, 2025. The third tranche of \$2.5 million is available until December 31, 2025, subject to the achievement of certain clinical milestones; the fourth tranche of \$2.5 million is available through December 31, 2025, subject to the achievement of a clinical milestone or satisfaction of certain capitalization requirements; and the final tranche of \$20.0 million is available through July 31, 2026, on such terms as may be agreed by the parties and subject to approval by SVB's credit committee. With the exception of the final tranche, and subject to achievement of the applicable milestones and other requirements with respect to each tranche, draw downs are at the Company's election. As of September 30, 2024, the Company has not drawn any funds under the Loan Agreement.

Interest will accrue on the term loan advances at a rate per annum that is equal to the greater of 8.50% and the prime rate and will be payable monthly in arrears. Principal payments on any term loan advances that are borrowed would commence on January 1, 2026, subject to extension to July 1, 2026, upon the satisfaction of certain milestones.

As security for its obligations under the Loan Agreement, the Company granted SVB a security interest in substantially all of the assets of the Company, other than its intellectual property.

## 7. 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 our common stock (the Lender Warrant). The Lender Warrant became exercisable for 73,649 shares upon closing (the Initial Lender Warrant), which represented 0.075% of the Company's common stock and common stock equivalents outstanding as of the day before the closing, on a fully-diluted basis, 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 will 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). The Remaining Lender Warrant under the Loan Agreement is considered an outstanding instrument upon closing of the Loan Agreement for accounting purposes. In accordance with Accounting Standards Codification (ASC) 815-40, *Derivatives and Hedging - Contracts in Entity's Own Equity*, the Remaining Lender Warrant is recognized at its fair value as a warrant liability given the variable settlement amount of the warrant shares and included in other non-current liabilities within the condensed balance sheets. The Lender Warrant expires on August 6, 2034.

### ***"At-the-Market" Equity Offering***

On August 10, 2022, the Company entered into a sales agreement (Sales Agreement) with Leerink Partners LLC (formerly SVB Securities 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. As of September 30, 2024, the Company may issue and sell up to approximately \$71.0 million in additional shares of its common stock under the ATM.

### ***Follow-On Offering***

On February 12, 2024, the Company completed an underwritten offering of 8,888,890 shares of its common stock at a price of \$4.50 per share and, to an investor in lieu of common stock, pre-funded warrants to purchase 2,222,271 shares of its common stock at a price of \$4.499 per each pre-funded warrant. The pre-funded warrants can be exercised at any time after issuance for an exercise price of \$0.001 per share, subject to certain ownership limitations. The Company received net proceeds of approximately \$46.8 million, after deducting underwriting discounts and commissions of approximately \$3.0 million and offering expenses of \$0.2 million.

As of September 30, 2024, total shares of common stock reserved for issuance, on an as-if converted basis, are as follows:

	September 30, 2024
Outstanding stock options and awards	11,146,572
Outstanding pre-funded warrants	7,104,853
Outstanding Lender Warrant	171,848
Shares available for further issuance under the 2024 Inducement Equity Incentive Plan	1,200,000
Shares available for further issuance under the 2021 Equity Incentive Plan	1,355,277
Shares available for further issuance under the 2021 Employee Stock Purchase Plan	1,767,746
<b>Total</b>	<b>22,746,296</b>



## 8.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	Amortized Cost	September 30, 2024		Unrealized Loss	Fair Value
			Unrealized Gain			
			(In thousands)			
Assets:						
Cash equivalents:						
Cash equivalents	Level 1	\$ 31	\$ —	\$ —	\$ —	\$ 31
Money market funds	Level 1	6,247	—	—	—	6,247
Marketable securities:						
U.S. treasuries	Level 1	50,299	53	(7)	(7)	50,345
Commercial paper	Level 2	5,901	11	—	—	5,912
Government agencies bonds	Level 2	14,962	21	(2)	(2)	14,981
Total financial assets		\$ 77,440	\$ 85	\$ (9)	\$ (9)	\$ 77,516

	Valuation Hierarchy	Amortized Cost	December 31, 2023		Unrealized Loss	Fair Value
			Unrealized Gain			
			(In thousands)			
Assets:						
Cash equivalents:						
Money market funds	Level 1	\$ 91	\$ —	\$ —	\$ —	\$ 91
U.S. treasuries	Level 1	3,595	—	—	—	3,595
Commercial paper	Level 2	34,901	—	(18)	—	34,883
Government agencies bonds	Level 2	6,389	1	—	—	6,390
Marketable securities:						
U.S. treasuries	Level 1	16,182	4	(15)	—	16,171
Commercial paper	Level 2	2,971	—	(2)	—	2,969
Government agencies bonds	Level 2	39,897	6	(82)	—	39,821
Total financial assets		\$ 104,026	\$ 11	\$ (117)	\$ —	\$ 103,920

Money market funds and U.S. treasury securities are classified as Level 1 because they are valued using quoted market prices in active markets for identical assets. Financial instruments classified within Level 2 of the fair value hierarchy are valued based on observable inputs or can be derived from non-binding quotes from the Company's investment managers, which are based on proprietary valuation models of independent pricing services. These models generally use inputs such as observable market data, quoted market prices for similar instruments, or historical pricing trends of a security relative to its peers.

The Company believes it is more likely than not that its marketable securities in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. To date, the Company has not

recorded any allowance for credit losses on its investment securities. Based upon its quarterly impairment review, the Company determined that the unrealized losses were not attributed to credit risk, but were primarily driven by the broader change in interest rates.

As of September 30, 2024, the fair value of available-for-sale marketable securities was \$71.2 million, all of which had remaining maturities of less than one year.

The Company's financial liability measured at fair value on a recurring basis consists of the Remaining Lender Warrant issued in connection with the Loan Agreement (see Note 7). The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company utilized the Black-Scholes option valuation model to fair value the warrant liability. The fair value is estimated using the Black-Scholes option-pricing model and adjusted for the likelihood of draw downs. The expected term is based on the remaining contractual term of the warrant. The Company estimates its expected stock volatility based on the historical volatility of a set of peer companies, which are publicly traded, and expects to continue to do so until it has adequate historical data regarding the volatility of its own publicly-traded stock price. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of measurement for time periods approximately equal to the expected term of the Lender Warrant. The Company uses an expected dividend yield of zero based on the fact that the Company has never paid cash dividends and does not expect to pay cash dividends in the foreseeable future. The warrant liability is subject to re-measurement at each balance sheet date, and any change in fair value is recognized as a gain or loss in our statement of operations and comprehensive loss. During the three and nine months ended September 30, 2024, the fair value of the warrant liability and its change were not material.

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.

## 9. Income Taxes

For the nine months ended September 30, 2024 and 2023, 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.

## 10. 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. Basic weighted-average shares of common stock outstanding includes the weighted-average effect of the Company's outstanding pre-funded warrants.

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:

	September 30,	
	2024	2023
Outstanding stock options and restricted stock units	11,146,572	9,319,127
Outstanding Lender Warrant	171,848	—
Total	<u>11,318,420</u>	<u>9,319,127</u>

## 11. Workforce Reduction

On May 14, 2024, the Company announced cost containment measures, including a committed plan to reduce its workforce (the Workforce Reduction) by approximately 22%. The cost containment measures align with the Company's focus on generating data from its clinical-stage gene therapy programs. The Workforce Reduction was completed as of September 30, 2024. During the nine-months ended September 30, 2024, the Company recognized \$1.4 million of aggregate charges, primarily related to employee cash severance and continuing health insurance benefits.

## 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, 2023, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 18, 2024, or Annual Report.*

*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. Our vision is to change the treatment paradigm for heart disease, and in doing so improve and extend the lives of millions of patients.

We are advancing a deep and diverse pipeline of disease-modifying targeted therapies that includes both gene therapies and small molecules discovered internally and developed using our extensive core capabilities to address rare or highly prevalent forms of heart disease. All of our programs are currently being assessed in clinical trials or are in the preclinical stage; we do not have any products approved for sale and have not generated any revenue to date.

Our lead investigational product candidates are TN-201, a gene therapy for myosin binding protein C3 (*MYBPC3*)-associated hypertrophic cardiomyopathy (HCM), TN-401, a gene therapy for plakophilin 2 (*PKP2*)-associated arrhythmogenic right ventricular cardiomyopathy (ARVC), and TN-301, a small molecule for heart failure with preserved ejection fraction (HFpEF).

TN-201 is our potential first-in-class and best-in-class gene therapy for adults and children with HCM due to *MYBPC3* gene mutations. These mutations result in a deficiency of myosin binding protein, 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 adeno-associated virus serotype 9 (AAV9) capsid and is designed to deliver a working *MYBPC3* gene to specific cells of the heart in order to produce cardiac myosin binding protein and thereby potentially slow or even reverse the course of *MYBPC3*-associated HCM following a single infusion.

In October 2023, we began dosing patients in the MyPEAK<sup>TM</sup>-1 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. We have completed Cohort 1 dosing at the 3E13 vg/kg dose in the MyPEAK-1 trial with no unexpected events or toxicities associated with TN-201 observed. Following review by an independent Data and Safety Monitoring Board (DSMB) of safety data from the first three MyPEAK-1 patients, the DSMB recommended that we proceed with the planned escalation to the 6E13 vg/kg dose, per protocol. MyPEAK-1 is now actively enrolling patients for Cohort 2 at several U.S. clinical sites and initial data from the trial is anticipated in December 2024.

To support our development efforts for TN-201 we are conducting two noninterventional studies: a study evaluating seroprevalence to AAV9 antibodies among adults with *MYBPC3*-associated HCM, and MyClimb, a prospective and retrospective global natural history study focused on pediatric patients with *MYBPC3* mutation-associated cardiomyopathy. The seroprevalence study has completed enrollment and data is under analysis. The objective of the MyClimb natural history study is to characterize the outcomes, burden of illness, risk factors, quality of life, and biomarkers associated with disease progression in pediatric patients with cardiomyopathy due to *MYBPC3* gene mutations, as well as related treatments and procedures. 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. In July 2024, we received rare pediatric disease designation from the FDA for TN-201 in *MYBPC3*-associated HCM. TN-201 has also been granted orphan drug designation from the FDA, orphan medicinal product designation from the European Commission (EC), and Fast Track Designation from the FDA.

TN-401 is our potential first-in-class and best-in-class 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.

In October 2023, the FDA provided clearance of our IND application to initiate clinical testing of TN-401. We plan to initiate patient dosing in RIDGE™-1, our Phase 1b multi-center, open-label clinical trial, designed to assess the safety, tolerability and efficacy of a one-time intravenous infusion of TN-401, in the fourth quarter of 2024 and have activated multiple clinical trial sites at leading cardiology centers with ARVC expertise. We intend to expand enrollment of RIDGE-1 outside the U.S. and received approval from the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA), Research Ethics Committee and Health Research Authority for our TN-401 Clinical Trial Authorization in June 2024.

In support of our development efforts for TN-401, we have initiated a global noninterventional study (RIDGE) to collect natural history and seroprevalence to AAV9 antibodies data among ARVC patients who carry pathogenic or likely pathogenic *PKP2* gene mutations. TN-401 has received orphan drug designation from the FDA and orphan medicinal product designation from the EC, as well as Fast Track Designation from the FDA.

TN-301 is our small molecule inhibitor of histone deacetylase-6 (HDAC6), initially being developed for the potential treatment of HFpEF. HFpEF is characterized by a stiffening of the heart muscle resulting in an inability for the left ventricle to relax and fill with oxygenated blood sufficient to meet the body's needs. There are several cellular processes thought to underlie the pathophysiology of HFpEF, including increases in fibrosis and inflammation and defects in metabolism. Although HFpEF accounts for approximately half of all heart failures, there are few proven treatment options.

In October 2023, 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. In preclinical studies, selective HDAC6 inhibition has been shown to have comparable efficacy to empagliflozin, a sodium-glucose cotransporter-2 (SGLT2) inhibitor which is approved for the treatment of HFpEF and co-administration of our HDAC6 inhibition with a SGLT2 inhibitor demonstrated additive benefit. Taken together, these data support continued development of TN-301 as a potential treatment for patients with HFpEF. We believe late-stage clinical development of TN-301 is best suited for development by or with a well-resourced partner.

In addition to our lead product candidates, we have multiple early-stage programs progressing through preclinical development using various therapeutic approaches, including gene addition, gene editing, gene silencing, and cellular regeneration to address other forms of rare and/or prevalent heart disease.

Our distinct suite of integrated capabilities supports our efforts to discover and develop disease-modifying treatments focused on heart disease. We also continue to invest in complementary new technologies and the optimization of our existing proprietary capabilities, including the use of human iPSC-derived cardiomyocyte disease models, machine learning and phenotypic screening, gene editing, AAV capsid engineering and novel promoter constructs to enable the discovery, design, delivery and development of therapeutics that are best suited to a given cardiovascular condition. We have also internalized and integrated both current Good Manufacturing Practices (cGMP) and non-GMP AAV manufacturing capabilities to support our emerging portfolio of gene therapy and

cellular regeneration product candidates. Our Genetic Medicines Manufacturing Center, a cGMP facility, is strategically located near our research labs and Manufacturing Technology Development Center, a non-GMP facility, in the San Francisco Bay Area to enable smooth scale-up of production to support our clinical studies and utilizes a modular, scalable design to produce AAV-based gene therapies under cGMP standards. We seek to build on existing proprietary capabilities with the aim of increasing the safety and efficacy of genetic medicines, accelerating early-stage discovery and preclinical optimization and reducing the overall cost of goods by increasing manufacturing productivity and scalability.

## Results of Operations

### Comparison of the Three Months Ended September 30, 2024 and 2023:

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

(in thousands, except percentages)	Three Months Ended September 30,		\$ Change	% Change
	2024	2023		
Operating expenses:				
Research and development	\$ 20,350	\$ 23,091	\$ (2,741)	(12%)
General and administrative	6,361	7,829	(1,468)	(19%)
Total operating expenses	26,711	30,920	(4,209)	(14%)
Loss from operations	(26,711)	(30,920)	4,209	(14%)
Other income, net:				
Interest income	1,080	1,776	(696)	(39%)
Other expense, net	(3)	1	(4)	NM
Total other income, net	1,077	1,777	(700)	(39%)
Net loss	<u>\$ (25,634)</u>	<u>\$ (29,143)</u>	<u>\$ 3,509</u>	(12%)

### 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 (CROs) to execute preclinical studies and clinical trials on our behalf, consulting fees and fees related to licensing agreements. 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. We enter into various agreements with CROs. Costs of certain research and development activities are recognized based on estimates from a number of factors, including an evaluation of the progress of the activities, as well as input from external service providers.

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

(in thousands, except percentages)	Three Months Ended September 30,		\$ Change	% Change
	2024	2023		
Personnel-related costs	\$ 7,834	\$ 9,658	\$ (1,824)	(19%)
Facility and laboratory costs	6,188	5,617	571	10%
Outside services	5,644	7,365	(1,721)	(23%)
Other research and development expenses	684	451	233	52%
Total research and development expenses	<u>\$ 20,350</u>	<u>\$ 23,091</u>	<u>\$ (2,741)</u>	(12%)

Research and development expenses were \$20.4 million and \$23.1 million for the three months ended September 30, 2024 and 2023, respectively. The year-over-year decrease of \$2.7 million, or 12%, was primarily due to:

- a decrease of \$1.8 million in employee-related costs primarily driven by a workforce reduction plan initiated in May 2024 (the Workforce Reduction).
- a decrease of \$1.7 million in outside services reflecting lower costs for outside lab services as there were no IND-enabling activities in 2024.

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. However, we expect our research and development expenses to generally remain flat for the remainder of 2024.

#### **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.

General and administrative expenses were \$6.4 million and \$7.8 million for the three months ended September 30, 2024 and 2023, respectively. The year-over-year decrease of \$1.5 million, or 19%, was primarily due to decreases in employee-related costs driven by the Workforce Reduction and lower professional fees.

#### **Interest Income**

Interest income primarily consists of interest earned on our cash, cash equivalents and investment balances. The interest income was \$1.1 million and \$1.8 million for the three months ended September 30, 2024 and 2023, respectively. The year-over-year decrease of \$0.7 million was primarily due to lower cash, cash equivalents and investment balances.

#### **Net Loss**

Net loss for the three months ended September 30, 2024, was \$25.6 million, compared to a net loss of \$29.1 million for the three months ended September 30, 2023.

#### **Comparison of the Nine Months Ended September 30, 2024 and 2023:**

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

(in thousands, except percentages)	Nine Months Ended September 30,		\$ Change	% Change
	2024	2023		
Operating expenses:				
Research and development	\$ 68,054	\$ 75,173	\$ (7,119)	(9%)
General and administrative	23,242	24,574	(1,332)	(5%)
Total operating expenses	91,296	99,747	(8,451)	(8%)
Loss from operations	(91,296)	(99,747)	8,451	(8%)
Other income, net:				
Interest income	3,925	5,586	(1,661)	(30%)
Other income, net	78	12	66	NM
Total other income, net	4,003	5,598	(1,595)	(28%)
Net loss	<u>\$ (87,293)</u>	<u>\$ (94,149)</u>	<u>\$ 6,856</u>	<u>(7%)</u>

### Research and Development Expenses

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

(in thousands, except percentages)	Nine Months Ended September 30,		\$ Change	% Change
	2024	2023		
Personnel-related costs	\$ 28,668	\$ 28,468	\$ 200	1%
Facility and laboratory costs	19,613	23,768	(4,155)	(17%)
Outside services	17,404	21,209	(3,805)	(18%)
Other research and development expenses	2,369	1,728	641	37%
Total research and development expenses	<u>\$ 68,054</u>	<u>\$ 75,173</u>	<u>\$ (7,119)</u>	<u>(9%)</u>

Research and development expenses were \$68.1 million and \$75.2 million for the nine months ended September 30, 2024 and 2023, respectively. The year-over-year decrease of \$7.1 million, or 9%, was primarily due to:

- a decrease of \$4.2 million in facility and laboratory costs, reflecting lower costs of supplies and materials and lower facility management fees; and
- a decrease of \$3.8 million in outside services reflecting lower outside lab service fees as there were no IND-enabling activities in 2024, partially offset by an increase in clinical trial related costs for TN-201 and TN-401.

### General and Administrative

General and administrative expenses were \$23.2 million and \$24.6 million for the nine months ended September 30, 2024 and 2023, respectively. The year-over-year decrease of \$1.3 million, or 5%, was primarily due to decreases in employee-related costs driven by the Workforce Reduction and lower professional fees.

We continue to support our research and development activities and business development opportunities, and incur professional service fees. In addition, 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. However, we expect our general and administrative expenses to generally remain flat for the remainder of 2024.

### Interest Income

Interest income primarily consists of interest earned on our cash, cash equivalents and investment balances. The interest income was \$3.9 million and \$5.6 million for the nine months ended September 30, 2024 and 2023, respectively. The year-over-year decrease of \$1.7 million was primarily due to lower cash, cash equivalents and investment balances.

### Net Loss

Net loss for the nine months ended September 30, 2024, was \$87.3 million, compared to a net loss of \$94.1 million for the nine months ended September 30, 2023.

### Liquidity and Capital Resources

#### Sources of Liquidity

Since our inception, we have not generated any revenue and we have incurred significant net losses and negative cash flows from operations. From our inception through September 30, 2024, we have funded our operations primarily from the sale and issuance of our equity securities. As of September 30, 2024, we had cash, cash equivalents and investments in marketable securities of \$79.5 million and an accumulated deficit of \$490.6 million.

#### Loan Agreement

On August 6, 2024, we entered into a Loan Agreement with Silicon Valley Bank (SVB), a division of First-Citizens Bank & Trust Company (the Loan Agreement). As of the filing date of this periodic report, under the Loan Agreement, we have the right to draw down \$20.0 million at our discretion, up to an additional \$5.0 million upon

the satisfaction of certain milestones and up to an additional \$20.0 million that may be available at SVB's discretion, subject to specified conditions.

#### ***Follow-on Offering***

On February 12, 2024, we completed an underwritten offering of 8,888,890 shares of our common stock at a price of \$4.50 per share and, to an investor in lieu of common stock, pre-funded warrants to purchase 2,222,271 shares of our common stock at a price of \$4.499 per pre-funded warrant under our registration statement on Form S-3 (File No. 333-266741). The pre-funded warrants can be exercised at any time after issuance for an exercise price of \$0.001 per share, subject to certain ownership limitations. We received net proceeds of approximately \$46.8 million, after deducting underwriting discounts and commissions of approximately \$3.0 million and other offering expenses of approximately \$0.2 million.

#### ***"At-the-Market" Equity Offering***

On August 10, 2022, we entered into a sales agreement (the Sales Agreement) with Leerink Partners LLC (formerly SVB Securities LLC). Pursuant to the Sales Agreement, we may sell from time to time up to an aggregate of \$75.0 million of our common stock through an "at-the-market" (ATM) offering defined in Rule 415 under the Securities Act. The \$75.0 million of common stock that may be offered, issued and sold under the Sales Agreement is included in the \$300.0 million of securities that may be offered, issued and sold by us under our registration statement on Form S-3 (File No. 333-266741). As of September 30, 2024, we may issue and sell up to approximately \$71.0 million in additional shares of our common stock under the ATM.

#### ***Funding Requirements***

We expect that we will continue to incur operating losses over the foreseeable future. Our operating expenses are expected to remain relatively flat for the next twelve months but may increase in the future, if and as we:

- continue to advance our lead gene therapy product candidates, TN-201 and TN-401;
- 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, cash equivalents and investments in marketable securities, along with the \$20.0 million of funds available under its Loan Agreement with SVB, 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 be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and



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:

	2024	Nine Months Ended September 30, (In thousands)	2023
Net cash provided by (used in):			
Operating activities	\$	(72,113)	\$ (80,148)
Investing activities		(12,972)	63,634
Financing activities		47,372	3,678
Net change in cash, cash equivalents and restricted cash	\$	<u>(37,713)</u>	\$ <u>(12,836)</u>

### **Operating Activities**

Net cash used in operating activities for the nine months ended September 30, 2024 was \$72.1 million, which consisted primarily of a net loss of \$87.3 million and a net change in operating assets and liabilities of \$6.9 million, partially offset by \$21.0 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 \$5.3 million and a decrease in operating lease liabilities of \$3.2 million, partially offset by a decrease of prepaid expenses and other current assets of \$1.1 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 \$12.7 million and depreciation and amortization of \$6.4 million.

Net cash used in operating activities for the nine months ended September 30, 2023 was \$80.1 million, which consisted primarily of a net loss of \$94.1 million and a net change in operating assets and liabilities of \$5.0 million, partially offset by \$19.0 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 \$3.3 million and a decrease in operating lease liabilities of \$3.1 million, partially offset by a decrease of prepaid expenses and other current assets of \$2.0 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 \$11.4 million and depreciation and amortization of \$6.5 million.

### **Investing Activities**

Net cash used in investing activities for the nine months ended September 30, 2024 was \$13.0 million, which consisted primarily of purchases of marketable securities of \$85.1 million, partially offset by proceeds from maturities of marketable securities of \$72.9 million.

Net cash provided by investing activities for the nine months ended September 30, 2023 was \$63.6 million, which consisted primarily of proceeds from maturities of marketable securities of \$105.5 million, partially offset by purchases of marketable securities of \$41.0 million.

### **Financing Activities**

Net cash provided by financing activities for the nine months ended September 30, 2024 was \$47.4 million, which primarily consisted of net proceeds from our February 2024 follow-on offering of \$46.8 million.

Net cash provided by financing activities for the nine months ended September 30, 2023 was \$3.7 million, which primarily consisted of proceeds from at-the-market sales of \$3.9 million, partially offset by payments of accrued offering costs.

### **Contractual Obligations and Other Commitments**

Except as otherwise described in Note 4 to our unaudited condensed financial statements included in this periodic report, 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, 2023.

### **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, 2023. There were no material changes to our critical accounting policies and estimates during the three and nine months ended September 30, 2024.

### **Recent Accounting Pronouncements**

See Note 2 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 of 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 company's 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 and 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, or 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 September 30, 2024 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 Loan Agreement requires us to comply with specified operating covenants and places restrictions on our operating and financial flexibility.
- 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.
- Due to our limited manufacturing experience there can be no assurance that we will be able to successfully manufacture product candidates to support our clinical development and commercialization plans.
- 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.

#### **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 could 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 September 30, 2024, we had an accumulated deficit of \$490.6 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 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;

- operating a manufacturing facility and 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;
- successful outputs from our capsid engineering and promotor and regulator 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, and 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.

***Our recent cost containment initiative, including our Workforce Reduction, may not result in the anticipated savings and could result in total costs and expenses that are greater than expected and could disrupt our business.***

On May 14, 2024, in alignment with our focus on generating data from our clinical-stage gene therapy programs, we announced cost containment measures, including the Workforce Reduction, which impacted approximately 22% of our workforce.

Our cost containment initiative, including the Workforce Reduction, may be disruptive to our operations. For example, the Workforce Reduction could yield unanticipated consequences, such as attrition beyond planned staff reductions, the loss of institutional knowledge and expertise, increased difficulties in our day-to-day operations, reduced employee morale and diversion of our management and employee attention from other business priorities. The Workforce Reduction could also harm our ability to attract and retain qualified personnel who are critical to our business, make it difficult for us to pursue new opportunities and initiatives and require us to hire qualified replacement personnel. We also may be required to take additional cost-saving measures in the future, including those involving personnel, and we may incur severance and other related costs.

If we experience excessive unanticipated inefficiencies or incremental costs in connection with the Workforce Reduction, we may be unable to meaningfully realize cost savings and we may incur expenses in excess of what we anticipate. If we are unable to realize the anticipated benefits from the Workforce Reduction and our other cost-saving measures, or if we experience significant adverse consequences from these measures, it could prevent us from meeting our strategic objectives and could adversely impact our results of operations and financial condition.

***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 in the near- and 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 September 30, 2024, we had \$79.5 million in cash, cash equivalents and investments in marketable securities. 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, including those in our Loan Agreement, 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. 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 \$20.0 million at our discretion, up to an additional \$5.0 million, subject to specified conditions, and up to an additional \$20.0 million may be made available to us at the lender's sole discretion. Our ability to draw down two tranche commitments totaling \$5.0 million in the aggregate is subject to our achievement, as determined by SVB in its discretion, of certain clinical milestones and the receipt of specified proceeds from equity financings and other qualified fundings. Our ability to draw down an additional tranche of \$20.0 million is 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 recently 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 the impacted tax years. 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, 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 are unable to optimize our manufacturing processes to produce product candidates that meet applicable regulatory standards, do not successfully initiate and complete our clinical trials in a timely manner 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 if 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 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 European Union (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 CTA, initiation of a clinical trial, receipt of marketing approval or our ability to commercialize our product candidates, or require us to suspend 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. Any clinical trial we initiate in the EU in the future will become subject to the provisions of the CTR. 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 contract research organizations, 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, including a finding that our product candidates have undesirable side effects or other unfavorable or unexpected characteristics or risks or non-compliance with regulatory requirements;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- the costs 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 clinical data entry or reporting by clinical sites;
- 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, Good Clinical Practices (GCP) or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner;
- 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, 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 simply due to the gravity of such patients' illnesses. 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, or 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. 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. 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 expect patient enrollment to be affected because our competitors have ongoing clinical trials for programs that are under development 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. 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;
- 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;
- patient referral practices of physicians;
- challenges associated with recruiting eligible patients;
- the ability to monitor patients adequately during and after treatment;

- 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 burden of the study protocol on patients, including conflicts with their work, family and personal activities; and
- 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.

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, including the Workforce Reduction, we are prioritizing the ongoing clinical development of our lead gene therapy programs. 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 determinations regarding 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.

***Interim, topline and preliminary 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 preliminary, interim or topline data from our clinical trials. These interim 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 topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data is available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. 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 interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, 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 preliminary 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 assure that the process works and the product candidate is made strictly and consistently in compliance with the process.

Problems with the manufacturing process, even minor deviations from the normal process, including during the manufacture of drug substance, drug product filling, labeling, packaging, storage and shipping and quality control and testing, could result in product defects, lot failures, product recalls, product liability claims or insufficient inventory. Additionally, we may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, or other comparable applicable foreign regulatory authorities' standards or specifications with consistent and acceptable production yields and costs.

Furthermore, should any of our manufacturing agreements with third parties be terminated for any reason, there are a limited number of manufacturers who would be suitable replacements, and it would take a significant amount of time to transition the manufacturing to a replacement. If we or our third-party manufacturers or suppliers are unable to produce sufficient quantities for preclinical studies or clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

***Due to our limited manufacturing experience, there can be no assurance that we will be able to successfully manufacture product candidates to support our clinical development and commercialization plans.***

We have fully integrated and internalized AAV manufacturing capabilities to support our gene therapy product candidates. However, to optimize our resources and to utilize extensive third-party experience in small molecule manufacturing, we intend to work with contract development and manufacturing organizations (CDMOs) for our small molecule programs.

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. Furthermore, maintaining manufacturing operations requires significant resources, management time and capital expenditures, particularly in areas relating to operations, quality, regulatory, facilities and information technology.

We cannot guarantee that our facility will be able to produce sufficient quantities of product candidates needed to support our preclinical studies and ongoing and planned clinical trials. We may face delays or increased costs in the production of clinical supply at our manufacturing facility. We also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to operate our manufacturing facility and processes. If we experience unanticipated employee shortage or turnover in any of these areas, we may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate from developing these capabilities, which may negatively affect our product development timelines or result in difficulties in maintaining compliance with applicable regulatory requirements.

Any delays in the ongoing development of our internal manufacturing capabilities may disrupt or delay the supply of our product candidates if we have not maintained a sufficient back-up supply of such product candidates.

It may also hamper our ability to further process improvement, maintain quality control, limit our reliance on contract manufacturers and protect our trade secrets and other intellectual property, and could adversely impact the development or commercialization of our product candidates. Moreover, if we were required to change manufacturing facilities during the clinical development process, we may also be required to conduct additional studies, make notifications to regulatory authorities, make additional filings to regulatory authorities, and obtain regulatory authority approval for the new facilities, which approval may be delayed or never received.

***Our manufacturing facilities will be subject to significant government regulations and approvals, which are often costly and could result in adverse consequences to our business if we 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 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 our 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 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.

***We may not be able to successfully manufacture our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing resulting approved products, if any.***

To date, our product candidates have been manufactured in quantities adequate for preclinical studies and our Phase 1 clinical trials for our lead product candidates. In order to conduct later-stage clinical trials for a product candidate and for commercialization of the resulting product if that product candidate is approved for sale, we will need to manufacture product candidates in larger quantities. 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.

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.

***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 as 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;
- 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.

***Adverse public perception or regulatory scrutiny of gene therapy technology or precision medicine for the treatment of heart diseases may negatively impact the developmental progress or commercial success of product candidates that we develop.***

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

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

***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 the Centers for Medicare & Medicaid Services (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 cause or are perceived to cause injury or 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 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 facilities 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;
- 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 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.

***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 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 or 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 their facilities 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. However, there can be no assurances that we will be able to obtain orphan designations for our product candidates.

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.4<sup>th</sup> 1299 (11<sup>th</sup> 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 – that is, the scope of the orphan-drug exclusivity is limited to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity. The applicable exclusivity period is ten years in Europe. The European 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. Under the current law, the rare pediatric disease priority review program will begin to sunset after December 20, 2024. The FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for a drug and that designation was granted by December 20, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. 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. In July 2024, we received rare pediatric disease designation from the FDA for TN-201 in 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 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 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.

Recently, 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. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), was passed, which substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U.S. pharmaceutical industry. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, some of which have been successful, that create considerable uncertainty for our business. Although the U.S. Supreme Court held in 2021 that Texas and other challengers had no legal standing to challenge the ACA, we cannot predict how future challenges will impact our business, or what other healthcare measures and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation may have on our business.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted, including aggregate reductions to Medicare payments to providers, effective April 1, 2013, which, through subsequent amendments, will remain in effect through 2032 and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These and future laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

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 July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at increasing competition for prescription drugs. In August 2022, Congress passed the Inflation Reduction Act of 2022 (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. The impact of these judicial challenges as well as future judicial challenges in view of the Supreme Court's overturn of the *Chevron* doctrine, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. 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, security and other processing of personal information.

Outside of the U.S., relevant legal requirements continue to evolve. 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 General Data Protection Regulation (GDPR), which imposes substantial obligations upon companies and new rights for individuals, 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 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 have increased our responsibility and 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 European Economic Area (EEA), United Kingdom (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 and Switzerland to the U.S., all of which 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 from the EEA and Switzerland 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 data privacy, protection and security laws, rules, regulations and standards 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. 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 and data protection imposing new and relatively burdensome obligations, and with substantial uncertainty over the



interpretation and application of these 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 federal Health Insurance Portability and Accountability Act of 1996 (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. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies.

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.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, 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 negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit 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. 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.

***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. When and if we become profitable, these changes may cause us to pay federal income taxes earlier under the revised tax law than under the prior law and may increase our total federal tax liability attributable to orphan drug programs and other research and development. In addition, the Inflation Reduction Act of 2022 imposes a 1% excise tax on certain repurchases of stock made on or after January 1, 2023. These changes could increase our total 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 founders and other scientific and clinical advisors and consultants, and our scientific and medical staff. The Workforce Reduction, and any future cost containment initiatives, could have an adverse impact on our ability to retain and recruit qualified personnel. 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 founders and other 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 founders 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, cyber-attacks and other hacking attempts by malicious third parties, which may 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 data breach, disruption or security incident resulting in any loss, destruction, unavailability, alteration, disclosure, dissemination of, or damage or unauthorized access to, our data, or any other data that we process or maintain or that is processed or maintained 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 development and commercialization of our product candidates could be delayed. 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 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, cybersecurity breaches or incidents, including those that cause loss, destruction, unavailability, alteration, dissemination of, or damage or unauthorized access to, our data, including personal data, assets and 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 or financial condition.

We also rely on third parties to support the development and manufacture of our product candidates, and any data breaches 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' data security practices is limited. Due to applicable laws, rules, regulations and standards or contractual obligations, we may be held responsible for any information security failure or cyber-attack attributed to our third-party service providers as they relate to the information we share with them. We maintain limited cybersecurity insurance and therefore the successful assertion of one or more large claims against us in connection with a breach or other cybersecurity-related matter 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 incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security incident. However, we cannot guarantee that we will be able to detect or prevent any such incidents, or that we can identify, remediate or otherwise address any such 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 data breach, disruption or security incident resulting in any loss, destruction, or alteration of, damage, unauthorized access to or inappropriate or unauthorized disclosure of or dissemination of, our data, including personal data, or other information that is processed or maintained on our behalf, or if any of these is believed or reported to have occurred, we could be exposed to litigation and governmental investigations and inquiries, the further development and commercialization of our product candidates could be delayed, and we could be subject to 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, including effects of the Russia-Ukraine and Middle East conflicts.

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. 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 United States Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the 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 that 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.

Third parties may assert patent infringement claims against us directed at any of our product candidates based on our 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. We cannot predict the breadth of claims that may be allowed or enforced in our patents, potential future patents or in third-party 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. 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. 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 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 patent applications or in-licensed patents, trade secrets or other intellectual property rights as an inventor or co-inventor. For example, 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 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 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 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 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 developmental 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 license 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.

***Intellectual property discovered through government funded programs may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.***

We have in-licensed, and we may develop, acquire or in-license in the future, certain patents, patent applications or other intellectual property generated using U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third-party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as march-in rights). If the U.S. government exercises its march-in rights in our current or future intellectual property rights generated using U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the U.S. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property, and may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U.S. or that under the circumstances domestic manufacture is not commercially feasible. Any failure by us to comply with federal regulations regarding intellectual property rights that were developed through the use of U.S. government funding could have a material adverse effect on our business, financial condition, results of operations, and prospects.

#### **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 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 each 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 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;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing 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 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, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate 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. 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 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;
- 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, collaborations or capital commitments;
- 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, such as the COVID-19 pandemic;
- 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.

### ***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 September 30, 2024, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 62% 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 a shelf registration statement on Form S-3 that became effective on August 17, 2022, which allows us to undertake various equity and debt offerings up to \$300.0 million (the Shelf Registration), and as of September 30, 2024, we have sold 34,854,373 shares of our common stock and pre-funded warrants to purchase 8,458,964 shares of our common stock pursuant to the Shelf Registration.

Moreover, certain holders of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act, would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. If these 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 Stock Market LLC (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 may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. 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, which may discourage lawsuits against us and our directors, officers and 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 September 30, 2024, 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**

<b>Exhibit Number</b>	<b>Description</b>	<b>Form</b>	<b>File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>
3.1	<a href="#">Composite Amended and Restated Certificate of Incorporation of Tenaya Therapeutics, Inc., as amended</a>	10-Q	001-40656	3.1	8-9-2023
3.2	<a href="#">Amended and Restated Bylaws of Tenaya Therapeutics, Inc.</a>	8-K	001-40656	3.1	3-21-2023
4.1*+	<a href="#">Warrant to Purchase Stock</a>				
10.1*+	<a href="#">Loan and Security Agreement by and between Silicon Valley Bank, a division of First-Citizens Bank &amp; Trust Company and Tenaya Therapeutics, Inc.</a>				
10.2	<a href="#">Tenaya Therapeutics, Inc. 2024 Inducement Equity Incentive Plan and related forms of stock option and restricted stock unit agreements</a>	8-K	001-40656	10.1	9-16-2024
31.1*	<a href="#">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.</a>				
32.1†	<a href="#">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.</a>				
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 the exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K. A copy of any omitted portions will be furnished to the SEC upon request.

† 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: November 6, 2024

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)

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**ACT**"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTIONS 6.3 AND 6.4 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

### WARRANT TO PURCHASE STOCK

This WARRANT TO PURCHASE STOCK (as amended and in effect from time to time, this "**Warrant**") is issued as of the issue date set forth on Schedule I hereto (the "**Issue Date**") by the company set forth on Schedule I hereto (the "**Company**") to SILICON VALLEY BANK, A DIVISION OF FIRST-CITIZENS BANK & TRUST COMPANY, in connection with that certain Loan and Security Agreement of even date herewith between them (as amended and/or modified and in effect from time to time, the "**Loan Agreement**"). The parties agree as follows:

#### SCHEDULE I. WARRANT PROVISIONS.

<u>Warrant Section</u>	<u>Warrant Provision</u>
Recitals – "Issue Date"	August 6, 2024.
Recitals – "Company"	<b>TENAYA THERAPEUTICS, INC.</b> , a Delaware corporation
1.1 – "Class"	Common Stock, \$0.0001 par value per share.
1.1 – "Exercise Price"	\$2.55 per Share.
1.2 – "Initial Shares"	73,649.
1.3(a) – "Tranche A Additional Shares"	The Tranche A Additional Shares Pool, multiplied by (x) the amount of the Tranche A Term Loan Advance (as defined in the Loan Agreement), divided by (y) \$15,000,000.
1.3(a) – Conditions for issuance of Tranche A Additional Shares	The making of each Tranche A Term Loan Advance (as defined in the Loan Agreement) to the Company in any amount.
1.3(a) – "Tranche A Additional Shares Pool"	49,099.
1.3(b) – "Tranche B Additional Shares"	The Tranche B Additional Shares Pool, multiplied by (x) the amount of the Tranche B Term Loan Advance (as defined in the Loan Agreement), divided by (y) \$5,000,000.
1.3(b) – Conditions for issuance of Tranche B Additional Shares	The making of each Tranche B Term Loan Advance (as defined in the Loan Agreement) to the Company in any amount.
1.3(a) – "Tranche B Additional Shares Pool"	24,550.
1.3(c) – "Tranche C Additional Shares"	The Tranche C Additional Shares Pool, multiplied by (x) the amount of the Tranche C Term Loan Advance (as defined in the Loan Agreement), divided by (y) \$2,500,000.
1.3(c) – Conditions for issuance of Tranche C Additional Shares	The making of each Tranche C Term Loan Advance (as defined in the Loan Agreement) to the Company in any amount.

<u>Warrant Section</u>	<u>Warrant Provision</u>
1.3(c) – “Tranche C Additional Shares Pool”	12,275.
1.3(d) – “Tranche D Additional Shares”	The Tranche D Additional Shares Pool, multiplied by (x) the amount of the Tranche D Term Loan Advance (as defined in the Loan Agreement), divided by (y) \$2,500,000.
1.3(d) – Conditions for issuance of Tranche D Additional Shares	The making of each Tranche D Term Loan Advance (as defined in the Loan Agreement) to the Company in any amount.
1.3(d) – “Tranche D Additional Shares Pool”	12,275.
4.1(b) – Share Percentage	0.175%.
6.1(a) – “Expiration Date”	August 6, 2034.
6.5 – “Holder Notice Address”	First-Citizens Bank & Trust Company FCC07 Warrant Investment Team 4300 Six Forks Road Raleigh, NC 27609 Telephone: [***] Email: [***]
6.5 – “Company Notice Address”	Tenaya Therapeutics, Inc. 171 Oyster Point Blvd., Suite 500 South San Francisco, CA 94080 Attn: [***] Email: [***]  With a copy (which shall not constitute notice) to:  Wilson Sonsini Goodrich & Rosati, P.C. 650 Page Mill Road Palo Alto, CA 94304 Attention: [***] Telephone: [***] Email: [***]

#### SECTION 1. RIGHT TO PURCHASE SHARES.

**1.1 Grant of Right.** For good and valuable consideration, the Company hereby grants to SILICON VALLEY BANK, A DIVISION OF FIRST-CITIZENS BANK & TRUST COMPANY (together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, “**Holder**”) the right, and Holder is entitled, to purchase from the Company up to the number of fully paid and non-assessable shares (as determined pursuant to Section 1.2 below) of the class set forth on Schedule I hereto (the “**Class**”), at a purchase price per Share set forth on Schedule I hereto (the “**Exercise Price**”), subject to the provisions and upon the terms and conditions set forth in this Warrant.

**1.2 Number of Shares.** This Warrant shall be exercisable for the number of initial shares of the Class as set forth on Schedule I hereto (the “**Initial Shares**”), plus the Additional Shares (as hereinafter defined), if any (collectively, and as may be adjusted from time to time in accordance with the provisions of this Warrant, the “**Shares**”).

1.3Additional Shares. This Warrant shall automatically become exercisable for the number of additional shares of the Class as set forth on Schedule I hereto (cumulatively and collectively, and as may be adjusted from time to time in accordance with the provisions of this Warrant, the "Additional Shares") upon the occurrence of events set forth on Schedule I hereto.

(a)"**Tranche A Additional Shares Pool**" shall have the meaning set forth on Schedule I hereto, as such number may be adjusted from time to time in accordance with the provisions of this Warrant (as if the Tranche A Additional Shares Pool constituted "Shares" hereunder for such purpose at all times from the Issue Date).

(b)"**Tranche B Additional Shares Pool**" shall have the meaning set forth on Schedule I hereto, as such number may be adjusted from time to time in accordance with the provisions of this Warrant (as if the Tranche B Additional Shares Pool constituted "Shares" hereunder for such purpose at all times from the Issue Date).

(c)"**Tranche C Additional Shares Pool**" shall have the meaning set forth on Schedule I hereto, as such number may be adjusted from time to time in accordance with the provisions of this Warrant (as if the Tranche C Additional Shares Pool constituted "Shares" hereunder for such purpose at all times from the Issue Date).

(d)"**Tranche D Additional Shares Pool**" shall have the meaning set forth on Schedule I hereto, as such number may be adjusted from time to time in accordance with the provisions of this Warrant (as if the Tranche D Additional Shares Pool constituted "Shares" hereunder for such purpose at all times from the Issue Date).

## SECTION 2.EXERCISE.

2.1Method of Exercise. Holder may exercise this Warrant in whole or in part at any time and from time to time prior to the expiration or earlier termination of this Warrant, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 2.2 below, a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Exercise Price for the Shares being purchased. Notwithstanding any contrary provision herein, to the extent that the original of this Warrant is an electronic original, in no event shall an original ink-signed paper copy of this Warrant be required for any exercise of a Holder's rights hereunder, nor shall this Warrant or any physical copy hereof be required to be physically surrendered at the time of any exercise hereof.

2.2Cashless Exercise. On any exercise of this Warrant, in lieu of payment of the aggregate Exercise Price in the manner specified in Section 2.1 above, Holder may elect to surrender to the Company Shares having an aggregate value equal to the aggregate Exercise Price. If Holder makes such election, the Company shall issue to Holder such number of fully paid and non-assessable Shares, subject to the BHCA Limits (as hereinafter defined), determined by the following formula:

$$X = Y(A-B)/A$$

where:

X = the number of Shares to be issued to Holder;

Y = the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Exercise Price);

A = the fair market value (as determined pursuant to Section 2.3 below) of one Share; and

B = the Exercise Price.

2.3Fair Market Value. If shares of the Company's common stock are then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market (a "**Trading Market**") and the Class is common stock, the fair market value of a Share shall be the closing price or last sale price of a share of the Company's common stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company (provided that solely for the purpose of determining the closing price or last sale price of a share pursuant to this Section 2.3, any Notice of Exercise

delivered pursuant to Section 6.5(iii) below will not give effect to the proviso contained therein). If shares of the Company's common stock are not then traded in a Trading Market, the Board of Directors of the Company shall determine the fair market value of a Share in its reasonable good faith judgment.

**2.4 Delivery of Certificate and New Warrant.** Within a reasonable time after Holder exercises this Warrant in the manner set forth in Sections 2.1 or 2.2 above, the Company shall deliver to Holder a certificate (or, in the case of uncertificated securities, provide notice of book entry) representing the Shares issued to Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired (or surrendered in payment of the aggregate Exercise Price).

**2.5 Replacement of Warrant.**

**(a) Paper Original Warrant.** To the extent that the original of this Warrant is a paper original, on receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form, substance and amount to the Company or, in the case of mutilation, on surrender of this Warrant to the Company for cancellation, the Company shall, within a reasonable time, execute and deliver to Holder, in lieu of this Warrant, a new warrant of like tenor and amount.

**(b) Electronic Original Warrant.** To the extent that the original of this Warrant is an electronic original, if at any time this Warrant is rejected by any person (including, but not limited to, paying or escrow agents) or any such person fails to comply with the terms of this Warrant based on this Warrant being presented to such person as an electronic record or a printout hereof, or any signature hereto being in electronic form, the Company shall, promptly upon Holder's request and without indemnity, execute and deliver to Holder, in lieu of electronic original versions of this Warrant, a new warrant of like tenor and amount in paper form with original ink signatures.

**2.6 Treatment of Warrant Upon Acquisition of Company.**

**(a) Acquisition.** "**Acquisition**" means any transaction or series of related transactions involving: (i) the sale, lease, exclusive license, or other disposition of all or substantially all of the assets of the Company; (ii) any merger or consolidation of the Company into or with another person or entity (other than a merger or consolidation effected exclusively to change the Company's domicile), or any other corporate reorganization, in which the stockholders of the Company in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the Company's (or the surviving or successor entity's) outstanding voting power immediately after such merger, consolidation or reorganization; or (iii) any sale or other transfer by the stockholders of the Company of shares representing at least a majority of the Company's then-total outstanding combined voting power. For the avoidance of doubt, "Acquisition" shall not include any sale and issuance by the Company of shares of its capital stock or of securities or instruments exercisable for or convertible into, or otherwise representing the right to acquire, shares of its capital stock to one or more investors for cash in a transaction or series of related transactions the primary purpose of which is a bona fide equity financing of the Company.

**(b) Treatment of Warrant in Cash/Public Acquisition.** In the event of an Acquisition in which the consideration to be received by the holders of the outstanding shares of the Class (in their capacity as such) consists solely of cash, solely of Marketable Securities (as hereinafter defined) or a combination of cash and Marketable Securities (a "**Cash/Public Acquisition**"), and the fair market value of one Share as determined in accordance with Section 2.3 above would be greater than the Exercise Price in effect as of immediately prior to the closing of such Cash/Public Acquisition, and Holder has not previously exercised this Warrant in full, then, in lieu of Holder's exercise of the unexercised portion of this Warrant, this Warrant shall, as of immediately prior to such closing (but subject to the occurrence thereof) automatically cease to represent the right to purchase Shares and shall, from and after such closing, represent solely the right to receive the aggregate consideration that would have been payable in such Acquisition on and in respect of all Shares for which this Warrant was exercisable as of immediately prior to the closing thereof, net of the aggregate Exercise Price therefor, as if such Shares had been issued and outstanding to Holder as of immediately prior to such closing, as and when such consideration is paid to the holders of the outstanding shares of the Class. In the event of a Cash/Public Acquisition in which the fair market value of one Share as determined in accordance with Section 2.3 above would be equal to or less than the Exercise Price in effect as of immediately prior to the closing of such Cash/Public Acquisition, then this Warrant will automatically and without further action of any party terminate as of immediately prior to such closing.

(c)Treatment of Warrant in non-Cash/Public Acquisition. Upon the closing of any Acquisition other than a Cash/Public Acquisition, the acquiring, surviving or successor entity shall assume this Warrant and the Company's obligations hereunder, and this Warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on and as of the closing of such Acquisition, at an aggregate Exercise Price equal to the aggregate Exercise Price in effect as of immediately prior to such closing, all subject to the BHCA Limits (as hereinafter defined) and further adjustment from time to time thereafter in accordance with the provisions of this Warrant.

(d)Marketable Securities. "**Marketable Securities**" means securities meeting all of the following requirements (determined as of immediately prior to the closing of the Acquisition): (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by Holder in connection with the Acquisition were Holder to exercise this Warrant on or prior to the closing thereof is then traded in a Trading Market, and (iii) following the closing of such Acquisition, Holder would not be restricted from publicly re-selling all of the issuer's shares and/or other securities that would be received by Holder in such Acquisition were Holder to exercise this Warrant in full on or prior to the closing of such Acquisition, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Acquisition. Notwithstanding the foregoing provisions of this Section 2.6(d), securities held in escrow or subject to holdback to cover indemnification-related claims shall be deemed to be Marketable Securities if they would otherwise be Marketable Securities but for the fact that they are held in escrow or subject to holdback to cover indemnification-related claims.

2.7BHCA Limitations. Notwithstanding any contrary provision herein, in no event may this Warrant be exercisable, in whole or in part, for or into a number of Shares in excess of the number of Shares that would result in Holder's ownership of Shares, when combined with any other interest in the Company held by Holder and any FCB Affiliate, equaling: (1) 33.32% of the Company's "total equity", as calculated in accordance with the Bank Holding Company Act of 1956, as amended (the "**BHCA**"), and any regulations, guidance and interpretations promulgated thereunder, including 12 CFR Part 225; or (2) 4.99% of any class of "voting securities" of the Company, as determined in accordance with the BHCA and any regulations, guidance and interpretations promulgated thereunder, including 12 CFR Part 225 (clauses (1) and (2) together, the "**BHCA Limits**"). To the extent the Holder would be, absent this section, entitled to receive Shares under this Warrant in excess of the BHCA Limits, Holder shall receive the right to cash consideration for the excess Shares, calculated in a manner consistent with this Section 2. The BHCA Limits shall apply to any transferee in receipt of this Warrant unless any such transfer to a transferee is made in a manner described under 12 CFR §225.9(a)(3)(ii). As used herein, "**FCB Affiliate**" means any entity that is controlled by, under the control of, or under common control with the Holder, with the term "control" as defined under the BHCA and regulations, guidance and interpretations promulgated thereunder.

### SECTION 3.CERTAIN ADJUSTMENTS TO THE SHARES, CLASS AND EXERCISE PRICE.

3.1Stock Dividends, Splits, Etc. If the Company declares or pays a dividend or distribution on the outstanding shares of the Class payable in additional shares of the Class (including fractional shares) or other securities or property (other than cash), then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without additional cost to Holder, the total number and kind of securities and property which Holder would have received had Holder owned the Shares of record as of the date the dividend or distribution occurred. If the Company subdivides the outstanding shares of the Class by reclassification or otherwise into a greater number of shares, the number of Shares purchasable hereunder shall be proportionately increased, even if such number would include fractional shares, and the Exercise Price shall be proportionately decreased. If the outstanding shares of the Class are combined or consolidated, by reclassification or otherwise, into a lesser number of shares, the Exercise Price shall be proportionately increased and the number of Shares shall be proportionately decreased, even if such number would include fractional shares.

3.2Reclassification, Exchange, Combination or Substitution. Upon any event whereby all of the outstanding shares of the Class are reclassified, exchanged, combined, substituted, or replaced for, into, with or by Company securities of a different class and/or series, then from and after the consummation of such event, "Class"



shall mean such securities and this Warrant will be exercisable for the number of such securities that Holder would have received had the Shares been outstanding on and as of the consummation of such event, at an aggregate Exercise Price equal to the aggregate Exercise Price in effect as of immediately prior to such event, all subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant. The provisions of this Section 3.2 shall similarly apply to successive reclassifications, exchanges, combinations, substitutions, replacements or other similar events.

**3.3 Adjustment to Exercise Price on Cash Dividend.** In the event that the Company at any time or from time to time prior to the exercise in full of this Warrant pays any cash dividend on the outstanding shares of the Class or makes any cash distribution on or in respect of all outstanding shares of the Class (other than a distribution of cash proceeds received by the Company in connection with an Acquisition described in Section 2.6(a)(i) above), then on and as of the date of each such dividend payment and/or distribution, the Exercise Price shall be reduced by an amount equal to the amount paid or distributed upon or in respect of each outstanding share of the Class; provided that in no event shall the Exercise Price be reduced below the then-par value, if any, of a share of the Class.

**3.4 No Fractional Share.** No fractional Share shall be issued upon exercise of this Warrant, and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of this Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash an amount equal to (a) such fractional interest, multiplied by (b)(i) the fair market value (as determined in accordance with Section 2.3 above) of a full Share, less (ii) the then-effective Exercise Price (the "**Fractional Share Value**"), unless Holder otherwise elects, in its sole discretion, to waive such payment. Notwithstanding any contrary provision herein, if this Warrant becomes exercisable for a fractional Share interest at any time or from time to time prior to the exercise in full of this Warrant, and the Company eliminates such fractional Share interest prior to any exercise of this Warrant, then the then-effective Exercise Price shall be reduced by an amount equal to the Fractional Share Value, unless Holder otherwise elects, in its sole discretion, to waive such reduction.

**3.5 Certificate as to Adjustments.** Within a reasonable time following each adjustment of the Exercise Price, Class and/or number of Shares pursuant to the terms of this Warrant, the Company, at its expense, shall deliver a certificate of its Chief Financial Officer or other authorized officer to Holder setting forth the adjustments to the Exercise Price, Class and/or number of Shares and the facts upon which such adjustments are based. The Company shall, at any time and from time to time within a reasonable time following Holder's written request and at the Company's expense, furnish Holder with a certificate of its Chief Financial Officer or other authorized officer setting forth the then-current Exercise Price, Class and number of Shares and the computations or other determinations thereof.

#### **SECTION 4. REPRESENTATIONS AND COVENANTS OF THE COMPANY.**

**4.1 Representations and Warranties.** The Company represents and warrants to, and agrees with, Holder as follows:

**(a)** [Intentionally Omitted.]

**(b)** The Initial Shares together with the Tranche A Additional Shares Pool, Tranche B Additional Shares Pool, Tranche C Additional Shares Pool, and Tranche D Additional Shares Pool collectively represent not less than the share percentage set forth on Schedule I hereto (the "**Share Percentage**"), calculated on and as of the Issue Date hereof on a fully-diluted, common stock-equivalent basis (but without excluding shares of capital stock that are not convertible into shares of common stock) assuming (i) the conversion into common stock of all outstanding securities and instruments (including, without limitation, securities deemed to be outstanding pursuant to clause (ii) of this Section 4.1(b)) convertible by their terms into shares of common stock (regardless of whether such securities or instruments are by their terms now so convertible), (ii) the exercise in full of all outstanding options, warrants (including, without limitation, this Warrant) and other rights to purchase or acquire shares of common stock or securities exercisable for or convertible into shares of common stock (regardless of whether such options, warrants or other rights to purchase or acquire are by their terms now exercisable); and (iii) the inclusion of all shares of common stock currently reserved for issuance under all of the Company's incentive stock and stock option plans as of the Issue Date and not currently subject to outstanding grants or options.

(c) All Shares which may be issued upon the exercise of this Warrant, shall, upon issuance, be duly authorized, validly issued, fully paid and non-assessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under the Company's Certificate of Incorporation or Bylaws, each as amended and in effect from time to time (the "**Charter Documents**"), any stockholder agreement (to the extent Holder is then a party thereto or otherwise subject thereto in accordance with the provisions of Section 5.4 below) or applicable federal and state securities laws. The Company covenants that it shall at all times cause to be reserved and kept available out of its authorized and unissued capital stock such number of shares of the Class and other securities as will be sufficient to permit the exercise in full of this Warrant.

(d) [Intentionally Omitted.]

4.2 Notice of Certain Events. If the Company proposes at any time to:

(a) declare any dividend or distribution upon the outstanding shares of the Class, whether in cash, stock or other securities or property and whether or not a regular cash dividend;

(b) offer for subscription or sale pro rata to all holders of the outstanding shares of the Class any additional securities of the Company (other than pursuant to contractual pre-emptive or first refusal rights);

(c) effect any redemption, reclassification, exchange, combination, substitution, reorganization or recapitalization of the outstanding shares of the Class;

(d) effect an Acquisition, or to liquidate, dissolve or wind up the Company; or

(e) [Intentionally Omitted];

then, in connection with each such event, the Company shall give Holder (pursuant to Section 6.5 below):

(1) in the case of the matters referred to in (a) and (b) above, at least seven (7) Business Days prior written notice of the earlier to occur of the effective date thereof or the date on which a record will be taken for such dividend, distribution, or subscription rights (and specifying the date on which the holders of outstanding shares of the Class will be entitled thereto) or for determining rights to vote, if any;

(2) in the case of the matters referred to in (c) and (d) above, at least seven (7) Business Days prior written notice of the date when the same will take place (and specifying the date on which the holders of outstanding shares of the Class will be entitled to exchange their shares for the securities or other property deliverable upon the occurrence of such event and such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such event giving rise to the notice); and

(3) [Intentionally Omitted].

4.3 Certain Company Information. The Company will provide such information requested by Holder from time to time, within a reasonable time following each such request, that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements.

## SECTION 5. REPRESENTATIONS AND COVENANTS OF HOLDER.

Holder represents and warrants to, and agrees with, the Company as follows:

### 5.1 Investment Representations.

(a) Purchase for Own Account. Except for the transfer of this Warrant from Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, to an FCB Affiliate as described in Section 6.4(b) below, this Warrant and the Shares to be acquired upon exercise hereof are being acquired for investment for Holder's account, not as a nominee or agent, and not with a view to the public resale or distribution within the meaning of the Act. Holder also represents that it has not been formed for the specific purpose of acquiring this Warrant or the Shares.

(b)Disclosure of Information. Holder is aware of the Company's business affairs and financial condition and has received or has had full access to all the information it considers necessary or appropriate to make an informed investment decision with respect to the acquisition of this Warrant and its underlying securities. Holder further has had an opportunity to ask questions of and receive answers from the Company regarding the terms and conditions of the offering of this Warrant and its underlying securities and to obtain additional information (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) necessary to verify any information furnished to Holder or to which Holder has access.

(c)Investment Experience. Holder understands that the purchase of this Warrant and its underlying securities involves substantial risk. Holder has experience as an investor in securities of companies in the development stage and acknowledges that Holder can bear the economic risk of such Holder's investment in this Warrant and its underlying securities for an indefinite period of time, and has such knowledge and experience in financial or business matters that Holder is capable of evaluating the merits and risks of its investment in this Warrant and its underlying securities and/or has a preexisting personal or business relationship with the Company and certain of its officers, directors or controlling persons of a nature and duration that enables Holder to be aware of the character, business acumen and financial circumstances of such persons.

(d)Accredited Investor Status. Holder is an "accredited investor" within the meaning of Regulation D promulgated under the Act.

(e)The Act. Holder understands that this Warrant and the Shares issuable upon exercise hereof have not been registered under the Act or registered or qualified under the securities laws of any state, and are issued in reliance upon specific exemptions therefrom, which exemptions depend upon, among other things, the bona fide nature of the Holder's investment intent as expressed herein. Holder understands that the Company is under no obligation to so register or qualify this Warrant, the Shares or such other securities. Holder understands that this Warrant and the Shares issued upon any exercise hereof are "restricted securities" under applicable federal and state securities laws and must be held indefinitely unless subsequently registered under the Act and registered or qualified under applicable state securities laws, or unless exemptions from such registration and qualification are otherwise available. Holder is aware of the provisions of Rule 144 promulgated under the Act.

5.2No Stockholder Rights. Without limiting any provision of this Warrant, Holder agrees that as a Holder of this Warrant it will not have any rights (including, but not limited to, voting rights) as a stockholder of the Company with respect to the Shares issuable hereunder unless and until the exercise of this Warrant and then only with respect to the Shares issued on such exercise.

5.3[Intentionally Omitted.]

5.4[Intentionally Omitted.]

5.5Confidential Information. Holder agrees to treat and hold all information provided by the Company pursuant to this Warrant in confidence in accordance with the provisions of Section 11.8 of the Loan Agreement (regardless of whether the Loan Agreement shall then be in effect).

## SECTION 6.MISCELLANEOUS.

### 6.1Term; Automatic Cashless Exercise Upon Expiration.

(a)Term. Subject to the provisions of Section 2.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Pacific time, on the expiration date set forth on Schedule I hereto (the "**Expiration Date**") and shall be void thereafter; provided that if the Company does not deliver to Holder written confirmation of the fair market value of a Share pursuant to Section 6.1(b) below, then the Expiration Date shall automatically be extended until the earlier to occur of (i) such date as the Company delivers such written confirmation and (ii) one (1) year after the Expiration Date.

(b)Automatic Cashless Exercise upon Expiration. In the event that, upon the Expiration Date, the fair market value of one Share as determined in accordance with Section 2.3 above is greater than the Exercise Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised

pursuant to Section 2.2 above as to all Shares for which it shall not previously have been exercised, and the Company shall, within a reasonable time following Holder's written request, deliver a certificate (or, in the case of uncertificated securities, provide notice of book entry) representing the Shares issued to Holder upon such exercise. If shares of the Company's common stock are not then traded in a Trading Market, the Company shall deliver to Holder, prior to the Expiration Date, written confirmation of the fair market value of a Share (as determined pursuant to Section 2.3 above) to be used in determining whether this Warrant shall automatically exercise on the Expiration Date pursuant to this Section 6.1(b).

**6.2Legends.** Each certificate or notice of book entry evidencing Shares shall be imprinted with a legend in substantially the following form (together with such additional legends as may be required by the Charter Documents or under any stockholder agreement (to the extent Holder is then a party thereto or otherwise subject thereto in accordance with the provisions of Section 5.4 above)):

THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE STOCK ISSUED BY THE ISSUER TO SILICON VALLEY BANK, A DIVISION OF FIRST-CITIZENS BANK & TRUST COMPANY, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

And, if then applicable, a legend in substantially the following form:

THE SECURITIES EVIDENCED BY THIS CERTIFICATE ARE SUBJECT TO CERTAIN RESTRICTIONS ON TRANSFERABILITY AND RESALE AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE STOCK ISSUED BY THE ISSUER TO SILICON VALLEY BANK, A DIVISION OF FIRST-CITIZENS BANK & TRUST COMPANY, A COPY OF WHICH MAY BE OBTAINED AT THE ISSUER'S PRINCIPAL OFFICE. SUCH RESTRICTIONS ARE BINDING ON TRANSFEREES OF THESE SECURITIES.

**6.3Compliance with Securities Laws on Transfer.** This Warrant and the Shares issued upon exercise hereof may not be transferred or assigned in whole or in part except in compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the Company). The Company shall not require Holder to provide an opinion of counsel if the transfer is to an FCB Affiliate or any other affiliate of Holder; provided that any such transferee is an "accredited investor" as defined in Regulation D promulgated under the Act.

**6.4Transfer Procedure.**

(a) Subject to the provisions of Section 6.3 and upon providing the Company with written notice, Holder (including any subsequent Holder) may transfer all or part of this Warrant or the Shares issued upon exercise of this Warrant to any transferee; provided that in connection with any such transfer: (i) Holder will give the Company notice of the portion of the Warrant and/or Shares being transferred with the name, address and taxpayer identification number of the transferee; (ii) Holder will surrender this Warrant, or the certificates or other evidence of such Shares or other securities, to the Company for reissuance to the transferee(s) (and to Holder if applicable); and (iii) any subsequent transferee shall make substantially the representations set forth in Section 5.1 above and shall agree in writing with the Company to be bound by all of the terms and conditions of this Warrant; and provided further, that the transfer of any Shares issued on exercise hereof shall be subject to the provisions of the Charter Documents and of the stockholder agreements to the extent Holder is then a party thereto or otherwise subject thereto in accordance with the provisions of Section 5.4 above.

(b) In the event of any transfer to an FCB Affiliate, the transfer requirements set forth in Section 6.4(a) above shall be satisfied by Holder delivering to the Company a Notice of Transfer in substantially the form attached hereto as Appendix 2; provided that: (i) Holder will not be required to surrender this Warrant pursuant to Section 6.4(a)(ii); (ii) the Company will note such FCB Affiliate as the Holder in the Company's records and, as applicable, with any transfer agent; and (iii) such FCB Affiliate will otherwise be deemed to be the "Holder" of this Warrant with respect to the transferred portion thereof. Such Notice of Transfer shall be deemed delivered and effective in accordance with Section 6.5 below, notwithstanding any request to confirm receipt or acknowledgment contained therein. By its acceptance of such transfer, such FCB Affiliate, on and as of the date of such transfer, hereby makes to the Company each of the representations and warranties set forth in Section 5.1 above and agrees to be bound by all of the terms and conditions of this Warrant as if it were the original Holder hereof.

(c) [Intentionally Omitted].

6.5 Notices. All notices and other communications hereunder from the Company to the Holder, or vice versa, shall be deemed delivered and effective (i) when given personally, (ii) on the third (3rd) Business Day after being mailed by first-class registered or certified mail, postage prepaid, (iii) upon transmission if given by electronic mail, provided that if such notice or other communication is not sent during the normal business hours of the recipient, it shall be deemed to have been sent at the opening of business on the next Business Day of the recipient, or (iv) on the first Business Day following delivery to a reliable overnight courier service, courier fee prepaid, in any case at such address as may have been furnished to the Company or Holder, as the case may be, in writing by the Company or such Holder from time to time in accordance with the provisions of this Section 6.5. All notices to Holder shall be addressed as set forth on Schedule I hereto (the "**Holder Notice Address**") until the Company receives notice of a change of address in connection with a transfer or otherwise. All notices to the Company shall be addressed as set forth on Schedule I hereto (the "**Company Notice Address**") until Holder receives notice of a change in address.

6.6 Amendment and Waiver. Notwithstanding any contrary provision herein or in the Loan Agreement, this Warrant may be amended and any provision hereof waived (either generally or in a particular instance and either retroactively or prospectively) only by an instrument in writing signed by Holder and any party against which enforcement of such amendment or waiver is sought.

6.7 Counterparts; Electronic Signatures; Status as Certificated Security. This Warrant may be executed by one or more of the parties hereto in any number of separate counterparts, all of which together shall constitute one and the same instrument. The Company, Holder and any other party hereto may execute this Warrant by electronic means and each party hereto recognizes and accepts the use of electronic signatures and the keeping of records in electronic form by any other party hereto in connection with the execution and storage hereof. To the extent that this Warrant or any agreement subject to the terms hereof or any amendment hereto is executed, recorded or delivered electronically, it shall be binding to the same extent as though it had been executed on paper with an original ink signature, as provided under applicable law, including, without limitation, any state law based on the Uniform Electronic Transactions Act. The fact that this Warrant is executed, signed, stored or delivered electronically shall not prevent the transfer by any Holder of this Warrant pursuant to Section 6.4 or the enforcement of the terms hereof. To the extent that the original of this Warrant is an electronic original, this Warrant, and any copies hereof, shall NOT be deemed to be a "certificated security" within the meaning of Section 8102(a)(4) of the California Commercial Code. Physical possession of the original of this Warrant or any paper copy thereof shall confer no special status to the bearer thereof.

6.8 Headings. The headings in this Warrant are for purposes of reference only and shall not limit or otherwise affect the meaning of any provision of this Warrant.

6.9 Business Days. "**Business Day**" means any day that is not a Saturday, Sunday or a day on which banks in California are closed.

## SECTION 7. GOVERNING LAW, VENUE AND JURY TRIAL WAIVER; JUDICIAL REFERENCE.

7.1 Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of California, without giving effect to its principles regarding conflicts of law.

**7.2Jurisdiction and Venue.** The Company and Holder each irrevocably and unconditionally submit to the exclusive jurisdiction of the State and Federal courts in Santa Clara County, California; provided, however, that nothing in this Warrant shall be deemed to operate to preclude Holder from bringing suit or taking other legal action in any other jurisdiction to enforce a judgment or other court order in favor of Holder. The Company expressly, irrevocably and unconditionally submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and the Company hereby irrevocably and unconditionally waives, to the fullest extent permitted by applicable law, any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby irrevocably and unconditionally consents to the granting of such legal or equitable relief as is deemed appropriate by such court. The Company hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to the Company in accordance with Section 6.5 of this Warrant and that service so made shall be deemed completed upon the earlier to occur of the Company's actual receipt thereof of three (3) days after deposit in the U.S. mails, proper postage prepaid.

**7.3Jury Trial Waiver.** **TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE COMPANY AND HOLDER EACH WAIVES ITS RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS WARRANT, THE LOAN AGREEMENT OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR THE PARTIES' AGREEMENT TO THIS WARRANT. EACH PARTY HERETO HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.**

**7.4Judicial Reference.** **WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES' AGREEMENT TO WAIVE THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY,** if the waiver of the right to a trial by jury in Section 7.3 above is not enforceable, the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties (or, if they cannot agree, by the Presiding Judge of the Santa Clara County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a jury, in Santa Clara County, California; and the parties hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure Sections 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and permanent injunctions and appointing receivers. All such proceedings shall be closed to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the Santa Clara County, California Superior Court for such relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings. The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The private judge shall oversee discovery and may enforce all discovery rules and orders applicable to judicial proceedings in the same manner as a trial court judge. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to California Code of Civil Procedure Section 644(a). Nothing in this Section 7.4 shall limit the right of any party at any time to exercise self-help remedies or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this Section 7.4.

**7.5Survival.** This Section 7 shall survive the termination of this Warrant.

*[Signature page follows]*

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**IN WITNESS WHEREOF**, the parties have caused this Warrant to Purchase Stock to be executed by their duly authorized representatives effective as of the Issue Date written above.

**COMPANY:**

**TENAYA THERAPEUTICS, INC.**

By: /s/ Leone Patterson

Name: Leone Patterson

Title: Chief Financial and Business Officer

**HOLDER:**

**FIRST-CITIZENS BANK & TRUST COMPANY**

By: /s/ Peter Sletteland

Name: Peter Sletteland

Title: Managing Director



APPENDIX 1

Form of Notice of Exercise of Warrant

1.The undersigned Holder hereby exercises its right to purchase \_\_\_\_\_ shares of the Common \_\_\_\_\_ Stock of TENAYA THERAPEUTICS, INC. (the "**Company**") in accordance with the attached Warrant to Purchase Stock.

[A. With respect to \_\_\_\_\_ such shares,] Holder hereby tenders payment of the aggregate Exercise Price for such shares as follows:

[ ☐ ] Check in the amount of \$\_\_\_\_\_ payable to order of the Company enclosed herewith

[ ☐ ] Wire transfer of immediately available funds to the Company's account

[ ☐ ] Cashless exercise pursuant to Section 2.2 of the Warrant, resulting in the issuance of \_\_\_\_\_ shares of the Common Stock of the Company

[ ☐ ] Other [Describe] \_\_\_\_\_

[B. In lieu of receiving \_\_\_\_\_ such shares, Holder hereby requests that the Company tenders payment to Holder in the amount of \$ \_\_\_\_\_ in accordance with Section 2.7 of the Warrant as follows:

[ ☐ ] Wire transfer of immediately available funds to Holder's account as follows: [Insert account details]

\_\_\_\_\_

[ ☐ ] Other [Describe] \_\_\_\_\_]

2.Please issue a certificate or certificates (or evidence of book entry) representing the shares in the name specified below:

\_\_\_\_\_  
Holder's Name

\_\_\_\_\_

\_\_\_\_\_  
(Address)

3.By its execution below and for the benefit of the Company, Holder hereby makes each of the representations and warranties set forth in Section 5.1 of the Warrant to Purchase Stock as of the date hereof.

HOLDER:

\_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

(Date): \_\_\_\_\_

Appendix 1

APPENDIX 2

Form of Notice of Transfer of Warrant Shares

(by email)

Re: Response Requested: Transfer of [Additional] Warrant Shares

Dear [Issuer Name],

Reference is made to the Warrant to Purchase Stock dated as of \_\_\_\_\_ (the "**Warrant**") issued by TENAYA THERAPEUTICS, INC. ("**Issuer**"), in favor of Silicon Valley Bank, a division of First-Citizens Bank & Trust Company ("**Holder**").

Holder hereby notifies Issuer that, as of \_\_\_\_\_ (the "**Transfer Date**"), Holder has transferred to \_\_\_\_\_ (Tax ID: \_\_\_\_\_), an affiliate of Holder ("**Transferee**"), the right to purchase [an additional] \_\_\_\_\_ common shares of Issuer which are currently exercisable (the "**Transferred Shares**") and all rights under the Warrant with respect to such Transferred Shares, pursuant to the transfer provisions contained in the Warrant. [Holder previously transferred to Transferee the right to purchase \_\_\_\_\_ [common] [preferred] shares of Issuer. In the aggregate, Holder has transferred to Transferee, and the Warrant is now exercisable for, a total of \_\_\_\_\_ common shares of Issuer.]

In connection with such transfer and as of the Transfer Date, Transferee hereby [makes] [reaffirms] to Issuer all representations and warranties set forth in the Warrant applicable to Holder. Furthermore, Transferee [agrees] [reaffirms its agreement] to be bound by all of the terms and conditions of the Warrant applicable to Holder.

***Issuer shall note in Issuer's records and, as applicable, with Issuer's transfer agent, that Transferee is the "Holder" with respect to the Transferred Shares.***

Transferee hereby [notifies] [reaffirms to] Issuer that all notices to Transferee should be addressed to Transferee as follows:

[[Transferee Name]

Attn: \_\_\_\_\_

[Transferee Address]

Telephone: \_\_\_\_\_

Email: \_\_\_\_\_]

***Please confirm your receipt and acknowledgment of this notice by replying to this email.***

Sincerely,

**Holder      Transferee**

FIRST-CITIZENS BANK & TRUST COMPANY [TRANSFEREE NAME]

[Officer Name]      [Officer Name]

[Officer Title]      [Officer Title]

1611752662.4

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CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [\*\*\*] INDICATES THAT INFORMATION HAS BEEN REDACTED.

## LOAN AND SECURITY AGREEMENT

This **LOAN AND SECURITY AGREEMENT** (this “**Agreement**”) is dated as of the Effective Date between **SILICON VALLEY BANK, A DIVISION OF FIRST-CITIZENS BANK & TRUST COMPANY** (“**Bank**”), and **TENAYA THERAPEUTICS, INC.**, a Delaware corporation (“**Borrower**”). The parties agree as follows:

### **1. LOAN AND TERMS OF PAYMENT**

**1.1**[Intentionally Omitted].

**1.2**[Intentionally Omitted].

**1.3**[Intentionally Omitted].

**1.4**[Intentionally Omitted].

**1.5**Term Loan Advances.

**(a) Availability.** Subject to the terms and conditions of this Agreement, upon Borrower's request, Bank shall make term loan advances to Borrower from time to time in four (4) tranches: “**Tranche A**”, “**Tranche B**”, “**Tranche C**”, and “**Tranche D**”. Subject to the terms and conditions of this Agreement, during the Tranche A Draw Period, upon Borrower's request, Bank shall make up to (3) term loan advances to Borrower under Tranche A, in an aggregate original principal amount not to exceed the Tranche A Availability Amount (each such advance is referred to herein as a “**Tranche A Term Loan Advance**” and, collectively, as the “**Tranche A Term Loan Advances**”). Subject to the terms and conditions of this Agreement and the achievement of the Tranche B Availability Milestone, upon Borrower's request, during the Tranche B Draw Period, Bank shall make one (1) term loan advance to Borrower under Tranche B, in an original principal amount equal to the Tranche B Availability Amount (the “**Tranche B Term Loan Advance**”). Subject to the terms and conditions of this Agreement and the achievement of the Tranche C Availability Milestone, upon Borrower's request, during the Tranche C Draw Period, Bank shall make one (1) term loan advance to Borrower under Tranche C, in an original principal amount equal to the Tranche C Availability Amount (the “**Tranche C Term Loan Advance**”). Subject to the terms and conditions of this Agreement and the achievement of the Tranche D Availability Milestone, upon Borrower's request, during the Tranche D Draw Period, Bank shall make one (1) term loan advance to Borrower under Tranche D, in an original principal amount equal to the Tranche D Availability Amount (the “**Tranche D Term Loan Advance**” and together with the Tranche A Term Loan Advances, Tranche B Term Loan Advance, and Tranche C Term Loan Advance, each a “**Term Loan Advance**” and collectively, the “**Term Loan Advances**”). The aggregate outstanding amount of the Term Loan Advances shall not, at any time, exceed Term Loan Availability Amount. Borrower may request Term Loan Advances as set forth on Schedule I hereto.

Additionally, at any time on or prior to July 31, 2026, Borrower may request that Bank make one (1) additional term loan advance available to Borrower in an original principal amount equal to Twenty Million Dollars (\$20,000,000) (the “**Uncommitted Accordion**”). Bank, in its sole and absolute discretion, may grant or deny such request from Borrower for a term loan advance under the Uncommitted Accordion. If, and only if, Bank, in its sole discretion, agrees to provide an additional term loan advance to Borrower under the Uncommitted Accordion, such term loan advance shall each be considered a “Term Loan Advance” hereunder and added to the definition thereof; provided that, the terms of the making of any advance under the Uncommitted Accordion shall be outlined in an amendment to this Agreement to be entered into by the parties hereto.

**(b) Repayment.** Borrower shall repay each Term Loan Advance as set forth in Schedule I hereto. All outstanding principal and accrued and unpaid interest under each Term Loan Advance, and all other

outstanding Obligations with respect to such Term Loan Advance, including the Final Payment, are due and payable in full on the Term Loan Maturity Date.

(c) Permitted Prepayment. Borrower shall have the option to prepay all or a portion of the outstanding Term Loan Advances; provided that any such prepayment shall be in a principal amount of at least Two Million Five Hundred Thousand Dollars (\$2,500,000); provided further that Borrower (i) delivers written notice to Bank of its election to prepay the Term Loan Advances at least five (5) days prior to such prepayment along with a notice of the portion of the principal amount being prepaid (which notice may be conditioned upon the consummation of a financing or other event and may be revoked by Borrower if such condition has not or will not occur on the proposed prepayment date), and (ii) pays, on the date of such prepayment (A) the outstanding principal plus accrued and unpaid interest with respect to the Term Loan Advances being prepaid, (B) the Prepayment Fee with respect to the principal amount of Term Loan Advances being prepaid, (C) the Final Payment with respect to the principal amount of the Term Loan Advances being prepaid, and (D) all other sums, if any, that shall have become due and payable with respect to the Term Loan Advances being prepaid, including interest at the Default Rate with respect to any past due amounts. Any voluntary prepayments made by Borrower pursuant to this Section 1.5(c) shall be applied to the remaining payments under the Term Loan Advances in the inverse order of maturity.

(d) Mandatory Prepayment Upon an Acceleration. If the Term Loan Advances are accelerated by Bank following the occurrence and during the continuance of an Event of Default, Borrower shall immediately pay to Bank an amount equal to the sum of (i) all outstanding principal plus accrued and unpaid interest with respect to the Term Loan Advances, (ii) the Prepayment Fee, (iii) the Final Payment, and (iv) all other sums, if any, that shall have become due and payable with respect to the Term Loan Advances, including interest at the Default Rate with respect to any past due amounts.

**1.6[Intentionally Omitted].**

**1.7[Intentionally Omitted].**

**1.8 Payment of Interest on the Credit Extensions.**

(a) Interest Payments.

(i) [Intentionally Omitted].

(ii) Term Loan Advances. Interest on the principal amount of each Term Loan Advance is payable as set forth on Schedule I hereto.

(b) Interest Rate.

(i) [Intentionally Omitted].

(ii) Term Loan Advances. Subject to Section 1.8(c), the outstanding principal amount of any Term Loan Advance shall accrue interest as set forth on Schedule I hereto.

(iii) All-In Rate. Notwithstanding any terms in this Agreement to the contrary, if at any time the interest rate applicable to any Obligations is less than zero percent (0.0%), such interest rate shall be deemed to be zero percent (0.0%) for all purposes of this Agreement.

(c) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, the outstanding Obligations shall bear interest at a rate per annum which is three percent (3.0%) above the rate that is otherwise applicable thereto (the "**Default Rate**") unless Bank otherwise elects from time to time in its sole discretion to impose a smaller or no increase. Fees and expenses which are required to be paid by Borrower pursuant to the Loan Documents (including, without limitation, Bank Expenses) but are not paid when due shall bear

interest until paid at a rate equal to the highest rate applicable to the Obligations. Payment or acceptance of the increased interest rate provided in this Section 1.8(c) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Bank.

(d) Adjustment to Interest Rate. Each change in the interest rate applicable to any amounts payable under the Loan Documents based on changes to the Prime Rate shall be effective on the effective date of any change to the Prime Rate and to the extent of such change.

(e) Interest Computation. Interest shall be computed as set forth on Schedule I hereto. In computing interest, the date of the making of any Credit Extension shall be included and the date of payment shall be excluded; provided, however, if any Credit Extension is repaid on the same day on which it is made, such day shall be included in computing interest on such Credit Extension.

**1.9 Fees and Expenses.** Borrower shall pay to Bank:

(a) Prepayment Fee. The Prepayment Fee, when due hereunder, which shall be fully earned and non-refundable as of such date;

(b) Final Payment. The Final Payment, when due hereunder, which shall be fully earned and non-refundable as of such date; and

(c) Bank Expenses. All Bank Expenses incurred through and after the Effective Date, when due (or, if no stated due date, upon demand by Bank). Borrower has paid to Bank a good faith deposit of Fifty Thousand Dollars (\$50,000) (the "**Good Faith Deposit**") to initiate Bank's due diligence review process. On the Effective Date, Bank will refund the Good Faith Deposit, minus out-of-pocket expenses.

Unless otherwise provided in this Agreement or in a separate writing by Bank, Borrower shall not be entitled to any credit, rebate, or repayment of any fees earned by Bank pursuant to this Agreement notwithstanding any termination of this Agreement or the suspension or termination of Bank's obligation to make loans and advances hereunder. Bank may deduct amounts owing by Borrower under the clauses of this Section 1.9 pursuant to the terms of Section 1.10(c). Bank shall provide Borrower written notice of deductions made pursuant to the terms of the clauses of this Section 1.9.

**1.10 Payments; Application of Payments; Debit of Accounts.**

(a) All payments (including prepayments) to be made by Borrower under any Loan Document shall be made in immediately available funds in Dollars, without setoff, counterclaim, or deduction, before 12:00 p.m. Pacific time on the date when due. Payments of principal and/or interest received after 12:00 p.m. Pacific time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment shall be due the next Business Day, and additional fees or interest, as applicable, shall continue to accrue until paid.

(b) Bank has the exclusive right to determine the order and manner in which all payments with respect to the Obligations may be applied. Borrower shall have no right to specify the order or the accounts to which Bank shall allocate or apply any payments required to be made by Borrower to Bank or otherwise received by Bank under this Agreement when any such allocation or application is not specified elsewhere in this Agreement.

(c) Bank may debit any of Borrower's deposit accounts maintained with Bank, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes Bank when due under the Loan Documents. These debits shall not constitute a set-off.

**1.11 Change in Circumstances.**

(a) Increased Costs. If any Change in Law shall: (i) impose, modify or deem applicable any reserve, special deposit, compulsory loan, insurance charge or similar requirement against assets of, deposits with or

for the account of, or advances, loans or other credit extended or participated in by, Bank, (ii) subject Bank to any Taxes (other than (A) Indemnified Taxes, (B) Taxes described in clauses (b) through (d) of the definition of Excluded Taxes, and (C) Connection Income Taxes) on its loans, loan principal, letters of credit, commitment, or other obligations, or its deposits, reserves, other liabilities or capital attributable thereto, or (iii) impose on Bank any other condition, cost or expense (other than Taxes) affecting this Agreement or Credit Extensions made by Bank, and the result of any of the foregoing shall be to increase the cost to Bank of making, converting to, continuing or maintaining any Credit Extension (or of maintaining its obligation to make any such Credit Extension), or to reduce the amount of any sum received or receivable by Bank hereunder (whether of principal, interest or any other amount) then, upon written request of Bank, Borrower shall promptly pay to Bank such additional amount or amounts as will compensate Bank for such additional costs incurred or reduction suffered.

(b)Capital Requirements. If Bank determines that any Change in Law affecting Bank regarding capital or liquidity requirements, has or would have the effect of reducing the rate of return on Bank's capital as a consequence of this Agreement, any term loan facility, or the Credit Extensions made by Bank to a level below that which Bank could have achieved but for such Change in Law (taking into consideration Bank's policies with respect to capital adequacy and liquidity), then from time to time upon written request of Bank, Borrower shall promptly pay to Bank such additional amount or amounts as will compensate Bank for any such reduction suffered.

(c)Delay in Requests. Failure or delay on the part of Bank to demand compensation pursuant to this Section 1.11 shall not constitute a waiver of Bank's right to demand such compensation; provided that, Borrower shall not be required to compensate Bank pursuant to subsection (a) for any increased costs incurred or reductions suffered more than nine (9) months prior to the date that Bank notifies Borrower of the Change in Law giving rise to such increased costs or reductions and of Bank's intention to claim compensation therefor (except that if the Change in Law giving rise to such increased costs or reductions is retroactive, then the nine (9) month period shall be extended to include the period of retroactive effect).

#### **1.12Taxes.**

(a)Payments Free of Taxes. Any and all payments by or on account of any obligation of Borrower under any Loan Document shall be made without deduction or withholding for any Taxes, except as required by Applicable Law. If any Applicable Law (as determined in the good faith discretion of Borrower) requires the deduction or withholding of any Tax from any such payment by Borrower, then (i) Borrower shall be entitled to make such deduction or withholding, (ii) Borrower shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with Applicable Law, and (iii) if such Tax is an Indemnified Tax, the sum payable by Borrower shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 1.12) Bank receives an amount equal to the sum it would have received had no such deduction or withholding been made.

(b)Payment of Other Taxes by Borrower. Without limiting the provisions of subsection (a) above, Borrower shall timely pay any Other Taxes to the relevant Governmental Authority in accordance with Applicable Law.

(c)Tax Indemnification. Without limiting the provisions of subsections (a) and (b) above, Borrower shall, and does hereby, indemnify Bank, within ten (10) days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this Section 1.12) payable or paid by Bank or required to be withheld or deducted from a payment to Bank and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to Borrower by Bank shall be conclusive absent manifest error.

(d)Evidence of Payments. As soon as practicable after any payment of Taxes by Borrower to a Governmental Authority pursuant to this Section 1.12, Borrower shall deliver to Bank a certified copy of a receipt issued by such Governmental Authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to Bank.

(e) Status of Bank. If Bank (including any assignee or successor) is entitled to an exemption from or reduction of withholding tax with respect to payments made under any Loan Document, it shall deliver to Borrower, at the time or times reasonably requested by Borrower, such properly completed and executed documentation reasonably requested by Borrower as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, Bank, if reasonably requested by Borrower, shall deliver such other documentation prescribed by Applicable Law or reasonably requested by Borrower as will enable Borrower to determine whether or not Bank is subject to backup withholding or information reporting requirements. If a payment made to Bank under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if Bank were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the Internal Revenue Code, as applicable), Bank shall deliver to Borrower at the time or times prescribed by law and at such time or times reasonably requested by Borrower such documentation prescribed by Applicable Law (including as prescribed by Section 1471(b)(3)(C)(i) of the Internal Revenue Code) and such additional documentation reasonably requested by Borrower as may be necessary for Borrower to comply with its obligations under FATCA and to determine that Bank has complied with Bank's obligations under FATCA or to determine the amount, if any, to deduct and withhold from such payment. Solely for purposes of the preceding sentence, "FATCA" shall include any amendments made to FATCA after the date of this Agreement. Without limiting the generality of the foregoing, Bank (including any assignee or successor) shall deliver executed copies of whichever of Internal Revenue Services ("IRS") Form W-9, IRS Form W-8BEN-E, IRS Form W-8ECI or W-8IMY is applicable, as well as any applicable supporting documentation or certifications on or about the date of this Agreement (and from time to time thereafter upon the reasonable request of Borrower).

### **1.13 Procedures for Borrowing.**

(a) [Intentionally Omitted].

(b) Term Loan Advances. Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan Advance set forth in this Agreement (which must be satisfied no later than 12:00 p.m. Pacific time on the applicable Funding Date), to obtain a Term Loan Advance, Borrower shall notify Bank (which notice shall be irrevocable) by 12:00 p.m. Pacific time on the Funding Date of the Term Loan Advance. Such notice shall be made through Bank's online banking platform by an individual duly authorized by an Administrator, by electronic mail or by telephone. In connection with any such notification, Borrower shall deliver to Bank by electronic mail or through Bank's online banking platform a completed Payment/Advance Form executed by an Authorized Signer and such other reports and information as Bank may reasonably request. Such Payment/Advance Form and other information (if any) must be received by Bank prior to 12:00 p.m. Pacific time on the requested Funding Date. Bank shall have determined to its satisfaction that any notice of or request for Term Loan Advances has been duly authorized by Borrower. Bank may rely on any notice given by a person whom Bank believes is an Authorized Signer or other individual authorized by an Administrator. Borrower will indemnify Bank for any loss Bank suffers due to such belief or reliance.

(c) Bank shall credit proceeds of a Credit Extension to the Designated Deposit Account. Bank may make Term Loan Advances under this Agreement based on instructions from an Authorized Signer or other individual authorized by an Administrator, or without instructions if such Term Loan Advances are necessary to meet Obligations which have become due.

## **2. CONDITIONS OF CREDIT EXTENSIONS**

**2.1 Conditions Precedent to Initial Credit Extension.** The effectiveness of this Agreement and Bank's obligation to make the initial Credit Extension shall be subject to the satisfaction or waiver, of the following conditions precedent:

(a) Loan Documents. Bank shall have received each of the following, each of which shall be in form and substance reasonably satisfactory to Bank:

(i) duly executed Loan Documents required to be delivered on the Effective Date;

(ii)duly executed warrant to purchase stock; and

(iii)duly executed Perfection Certificate of Borrower.

(b)Corporate Borrowing Certificates (or equivalent Officers' Certificates); Certified Operating Documents; Good Standing Certificates. Bank shall have received (i) certificate duly executed by a Responsible Officer or secretary of Borrower with respect to Borrower attaching: (A) Operating Documents of Borrower and (B) Borrowing Resolutions, and (ii) long-form good standing certificates of Borrower certified by the Secretary of State of the State of Delaware and good standing certificates from the Secretary of State (or equivalent agency) of each other jurisdiction in which Borrower is qualified to conduct business, in each case as of a date no earlier than 30 days prior to the Effective Date.

(c)Due Diligence. Bank shall have (i) completed a due diligence investigation of the Borrower, and with results, satisfactory to Bank and shall have been given such access to the management, records, books of account, contracts and properties of Borrower and shall have received such financial, business and other information regarding each of the foregoing Persons and businesses as it shall have requested received; (iii) received certified copies, dated as of a recent date, of searches for financing statement filed in the central filing office of the State of Delaware, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released, and Intellectual Property search results, and (iv) received all asset appraisals, field audits, and such other reports and certifications, as Bank has reasonably requested.

(d)Patriot Act, etc. Bank shall have received all documentation and other information requested (including beneficial ownership information) in connection with applicable "know your customer" and anti-money-laundering rules and regulations, including the USA Patriot Act, and Borrower shall have satisfied all requirements related thereto.

(e)Fees and Expenses. Bank shall have received payment of the fees and Bank Expenses then due as specified in Section 1.9 hereof.

(f)Other. On the Effective Date, Bank shall have received such other documents or certificates, and completion of such other matters, as Bank may reasonably deem necessary or appropriate.

**2.2Conditions Precedent to all Credit Extensions.** Bank's obligation to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

(a)receipt of Borrower's Credit Extension request and the related materials and documents as required by and in accordance with Section 1.13;

(b)the representations and warranties in this Agreement shall be true and correct in all material respects as of the date of any Credit Extension request and as of the Funding Date of each Credit Extension; provided, however, such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true and correct in all material respects as of such date, and no Default or Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in this Agreement remain true and correct in all material respects; provided, however, such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true and correct in all material respects as of such date; and

(c)Bank determines to its satisfaction that there has not been a (i) material impairment in the general affairs, management, results of operation or financial condition of Borrower, nor any material adverse deviation by Borrower from the business plan of Borrower presented to and accepted by Bank as of the Effective Date



(or from a business plan of Borrower presented to and accepted by Bank subsequent to the Effective Date pursuant to Section 5.3), or (ii) Material Adverse Change.

**2.3Covenant to Deliver.** Borrower shall deliver to Bank each item required to be delivered to Bank under this Agreement as a condition precedent to any Credit Extension. A Credit Extension made prior to the receipt by Bank of any such item shall not constitute a waiver by Bank of Borrower's obligation to deliver such item, and the making of any Credit Extension in the absence of a required item shall be in Bank's sole discretion.

### **3. CREATION OF SECURITY INTEREST**

#### **3.1 Grant of Security Interest.**

(a) Borrower hereby grants Bank, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Bank, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof.

(b) Borrower acknowledges that it previously has entered, or may in the future enter, into Bank Services Agreements with Bank. Regardless of the terms of any Bank Services Agreement, Borrower agrees that any amounts Borrower owes Bank thereunder shall be deemed to be Obligations hereunder and that it is the intent of Borrower and Bank to have all such Obligations secured by the first priority perfected security interest in the Collateral granted herein (subject to Permitted Liens).

**3.2 Authorization to File Financing Statements.** Borrower hereby authorizes Bank to file financing statements, without notice to Borrower, with all jurisdictions deemed necessary or appropriate by Bank to perfect or protect Bank's interest or rights hereunder, including a notice that any disposition of the Collateral in violation of this Agreement, by either Borrower or any other Person, shall be deemed to violate the rights of Bank under the Code. Such financing statements may indicate the Collateral as "all assets of the Debtor" or words of similar effect.

**3.3 Termination.** If this Agreement is terminated, Bank's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as Bank's obligation to make Credit Extensions has terminated, Bank shall, at Borrower's sole cost and expense, terminate its security interest in the Collateral and all rights therein shall revert to Borrower and Bank shall take such actions as may be reasonably requested by Borrower to evidence such repayment and release (including delivery of a payoff letter and filings of UCC-3 termination statements (or authorizing Borrower to file such UCC-3 termination statements)). In the event (a) all Obligations (other than inchoate indemnity obligations), except for Bank Services, are satisfied in full, and (b) this Agreement is terminated, Bank shall terminate the security interest granted herein upon Borrower providing cash collateral acceptable to Bank in its sole discretion for Bank Services, if any. In the event such Bank Services consist of outstanding Letters of Credit, Borrower shall provide to Bank cash collateral in an amount equal to at least (i) one hundred five percent (105.0%) of the face amount of all such Letters of Credit denominated in Dollars and (ii) one hundred ten percent (110.0%) of the Dollar Equivalent of the face amount of all such Letters of Credit denominated in a Foreign Currency, plus, in each case, all interest, fees, and costs due or estimated by Bank in its commercially reasonable discretion to become due in connection therewith, to secure all of the Obligations relating to such Letters of Credit.

### **4. REPRESENTATIONS AND WARRANTIES**

Borrower represents and warrants as follows:

#### **4.1 Due Organization, Authorization; Power and Authority.**

(a) Borrower and each of its Subsidiaries are each duly existing and in good standing as a Registered Organization in their respective jurisdiction of formation and are qualified and licensed to do business and in good standing in any jurisdiction in which the conduct of their respective business or their ownership of property

requires that they be qualified except where the failure to do so could not reasonably be expected to have a material adverse effect on Borrower's business or operations.

(b) All information set forth on the Perfection Certificate pertaining to Borrower and each of its Subsidiaries is true and correct (it being understood and agreed that Borrower may from time to time update certain information in the Perfection Certificate after the Effective Date to the extent permitted by one or more specific provisions in this Agreement and the Perfection Certificate shall be deemed to be updated to the extent such notice is provided to Bank of such permitted update).

(c) The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's or any such Subsidiary's organizational documents, (ii) contravene, conflict with, constitute a default under or violate any material Applicable Law, (iii) contravene, conflict with or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or any of its Subsidiaries or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect or in connection with the security interests granted pursuant hereto), or (v) conflict with, contravene, constitute a default or breach under, or result in or permit the termination or acceleration of, any material agreement by which Borrower or any of its Subsidiaries is bound. Neither Borrower nor any of its Subsidiaries are in default under any agreement to which it is a party or by which it is bound in which the default could reasonably be expected to have a material adverse effect on Borrower's or any of its Subsidiary's business or operations.

#### **4.2 Collateral.**

(a) The security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral (subject to Permitted Liens). Borrower has good title to, rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien hereunder, free and clear of any and all Liens except Permitted Liens.

(b) Borrower has no Collateral Accounts at or with any bank or financial institution other than Bank or Bank's Affiliates except for the Collateral Accounts described in the Perfection Certificate delivered to Bank (or as updated to the extent permitted by one or more specific provisions in this Agreement) in connection herewith and which Borrower has taken such actions as are necessary to give Bank a perfected security interest therein, pursuant to the terms of Section 5.9(c) or will take such actions pursuant to the terms of Section 5.18(c). The Accounts are bona fide, existing obligations of the Account Debtors.

(c) The Collateral is not in the possession of any third party bailee (such as a warehouse) except as otherwise provided in the Perfection Certificate or as permitted pursuant to Section 6.2. None of the components of the Collateral shall be maintained at locations other than as provided in the Perfection Certificate or as permitted pursuant to Section 6.2.

(d) All Inventory (if any) is in all material respects of good and marketable quality, free from material defects.

(e) Borrower owns, or possesses the right to use to the extent necessary in its business, all Intellectual Property, licenses and other intangible assets that are used in the conduct of its business as now operated, except to the extent that such failure to own or possess the right to use such asset would not reasonably be expected to have a material adverse effect on Borrower's business or operations, and no such asset, to the best knowledge of Borrower, conflicts with the valid Intellectual Property, license, or intangible asset of any other Person to the extent that such conflict could reasonably be expected to have a material adverse effect on Borrower's business or operations.

(f) Except as noted on the Perfection Certificate or for which notice has been given to Bank pursuant to and in accordance with Section 5.11(c), Borrower is not a party to, nor is it bound by, any Restricted License.

#### **4.3[Intentionally Omitted].**

**4.4Litigation.** Other than as set forth in the Perfection Certificate or as disclosed to Bank pursuant to Section 5.3(h), there are no actions, investigations or proceedings pending or, to the knowledge of any Responsible Officer, threatened in writing by or against Borrower or any of its Subsidiaries which would reasonably be expected to result in damages or costs, including settlement payments, to Borrower of more than, individually or in the aggregate, Five Hundred Thousand Dollars (\$500,000) not covered by independent third party insurance as to which liability has been accepted by the carrier providing such insurance.

**4.5Financial Statements; Financial Condition.** All consolidated financial statements for Borrower and any of its Subsidiaries delivered to Bank by submission to the Financial Statement Repository or otherwise submitted to Bank fairly present in all material respects Borrower's consolidated financial condition as at their dates and Borrower's consolidated results of operations for the periods covered thereby, subject, in the case of unaudited financial statements, to normal year-end adjustments and the absence of footnote disclosures. There has not been any material deterioration in Borrower's consolidated financial condition since the date of the most recent financial statements submitted to the Financial Statement Repository or otherwise submitted to Bank.

**4.6Solvency.** The fair salable value of Borrower's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of Borrower's liabilities; Borrower is not left with unreasonably small capital after the transactions in this Agreement; and Borrower and each of its Subsidiaries are able to pay their debts (including trade debts) as they mature.

**4.7Regulatory Compliance.** Borrower is not required to register as an "investment company" under the Investment Company Act of 1940, as amended. Borrower is not engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries have complied with all Applicable Law, and have not violated any Applicable Law, except where the non-compliance with which or violation of which could not reasonably be expected to have a material adverse effect on Borrower's business or operations. Borrower and each of its Subsidiaries have duly complied with, and their respective facilities, business, assets, property, leaseholds, real property and Equipment are in compliance with, Environmental Laws, except where the failure to do so could not reasonably be expected to have a material adverse effect on Borrower's business or operations; there have been no outstanding citations, notices or orders of non-compliance issued to Borrower or any of its Subsidiaries or relating to their respective facilities, businesses, assets, property, leaseholds, real property or Equipment under such Environmental Laws that could reasonably be expected to have a material adverse effect on Borrower's business or operations. Borrower and each of its Subsidiaries have obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

**4.8Subsidiaries; Investments.** Borrower does not own any stock, unit, membership interest, partnership, or other ownership interest or other equity securities except for Permitted Investments.

#### **4.9Tax Returns and Payments; Pension Contributions.**

(a) Borrower and each of its Subsidiaries have timely filed, or submitted extensions for, all required federal and state income tax and all other material tax returns and reports, and Borrower and each of its Subsidiaries have timely paid all federal and state income taxes and all other material foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower and each of its Subsidiaries except (i) to the extent such taxes, assessments, deposits or contributions are being contested in good faith by appropriate proceedings promptly instituted and diligently conducted, so long as such reserve or other appropriate provision, if any, as shall be required in conformity with GAAP shall have been made therefor, or (ii) if such taxes, assessments, deposits and contributions do not, individually or in the aggregate, exceed Fifty Thousand Dollars (\$50,000). Borrower is unaware of any claims or adjustments proposed for any of Borrower's or any of its Subsidiary's prior tax years which could result in additional taxes becoming due and payable by Borrower or any of its Subsidiaries in excess of Fifty Thousand Dollars (\$50,000) in the aggregate.

(b)Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries has withdrawn from participation in, and has not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

**4.10Full Disclosure.** No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any written report, written certificate or written statement submitted to the Financial Statement Repository or otherwise submitted to Bank, as of the date such representation, warranty, or other statement was made, taken together with all such reports, certificates and written statements submitted to the Financial Statement Repository or otherwise submitted to Bank and Borrower's filings with the SEC, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the written reports, written certificates or written statements not misleading in light of the circumstances under which they were made (it being recognized by Bank that the projections and forecasts provided by Borrower or any of its Subsidiaries in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

**4.11Sanctions.** Neither Borrower nor any of its Subsidiaries is: (a) in violation of any Sanctions; or (b) a Sanctioned Person. Neither Borrower nor any of its Subsidiaries, directors, officers, employees, agents or Affiliates: (i) conducts any business or engages in any transaction or dealing with any Sanctioned Person, including making or receiving any contribution of funds, goods or services to or for the benefit of any Sanctioned Person; (ii) deals in, or otherwise engages in any transaction relating to, any property or interests in property blocked pursuant to any Sanctions; (iii) engages in or conspires to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in any Sanctions; or (iv) otherwise engages in any transaction that could cause Bank to violate any Sanctions.

**4.12Healthcare Permits.** (a) Borrower and each of its Subsidiaries have obtained all Healthcare Permits and other rights from, and have made all declarations and filings with, all applicable Governmental Authorities, all self-regulatory authorities and all courts and other tribunals necessary to engage in the management and/or operation of their respective businesses; (b) each such Healthcare Permit is valid and in full force and effect, and Borrower and each of its Subsidiaries are in compliance with the terms and conditions of all such Healthcare Permits; and (c) neither Borrower nor any of its Subsidiaries has received notice from any Governmental Authority with respect to the revocation, suspension, restriction, limitation or termination of any Healthcare Permit nor, to the knowledge of Borrower or any of its Subsidiaries, is any such action proposed or threatened in writing.

**4.13Compliance with Healthcare Laws.**

(a)Borrower is in compliance in all material respects with all applicable Healthcare Laws. Without limiting the generality of the foregoing, Borrower has not received written notice by a Governmental Authority of any violation (or of any investigation, audit, or other proceeding involving allegations of any violation) of any Healthcare Laws, and no investigation, inspection, audit or other proceeding involving allegations of any violation is, to the knowledge of Borrower, threatened in writing or contemplated.

(b)To the knowledge of Borrower, Borrower is not in default or violation in any material respect of any Healthcare Law which is applicable to Borrower or its respective assets or the conduct of its respective businesses and Borrower has not been debarred or excluded from participation under a state or federal health care program, including any state or federal workers compensation program.

(c)Borrower is not a party to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders or similar agreements with or imposed by any Governmental Authority.

**5.AFFIRMATIVE COVENANTS**

Borrower shall do all of the following:

**5.1 Use of Proceeds.** Cause the proceeds of the Credit Extensions to be used solely (a) as working capital or (b) to fund its general corporate purposes, and not for personal, family, household or agricultural purposes, and not in furtherance of an offer, payment, promise to pay, or authorization of the payment or giving of money, or anything else of value, to any Person in violation of any applicable anti-corruption law.

**5.2 Government Compliance.**

(a) Maintain its and all of its Subsidiaries' legal existence (except as permitted under Section 6.3 with respect to Subsidiaries only) and good standing in their respective jurisdictions of formation and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a material adverse effect on Borrower's business or operations. Borrower shall comply, and have each Subsidiary comply with all Applicable Law, except where the non-compliance with which could not reasonably be expected to have a material adverse effect on Borrower's business or operations.

(b) Obtain all of the Governmental Approvals necessary for the performance by Borrower and each of its Subsidiaries of their obligations under the Loan Documents to which it is a party, including any grant of a security interest in the Collateral to Bank. Borrower shall promptly provide copies of any such obtained Governmental Approvals to Bank.

(c) Cause the operations and property of Borrower, each of its Subsidiaries to comply in all material respects with all applicable Healthcare Laws. Without limiting the foregoing, the operations and property of Borrower and each of its Subsidiaries shall comply, to the extent applicable, with HIPAA in all material respects. Borrower established and maintains a corporate compliance program that (i) addresses the material Requirements of Law, including all applicable Healthcare Laws, of Governmental Authorities having jurisdiction over its business and operations, and (ii) has been structured to account for any applicable guidance issued by the U.S. Department of Health and Human Services regarding characteristics of effective corporate compliance programs. As of the Effective Date, Borrower has delivered to Bank an accurate and complete copy of each material report, study, survey or other document of which Borrower has knowledge that addresses or otherwise relates to the compliance by Borrower and each of its Subsidiaries, with applicable Healthcare Laws.

**5.3 Financial Statements, Reports.** Deliver to Bank by submitting to the Financial Statement Repository:

(a) Bank Account Statements. Within thirty (30) days after the end of each calendar month, a copy of Borrower's account statement for the most recently ended calendar month for each bank account maintained outside of Bank;

(b) Compliance Statement. Together with the statements set forth in Section 5.3(a) and Section 5.3(d), a duly completed Compliance Statement, confirming that as of the end of such month or quarter (as applicable), Borrower was in full compliance with all of the terms and conditions of this Agreement, and setting forth calculations showing compliance with the financial covenants set forth in this Agreement (if any) and such other information as Bank may reasonably request;

(c) Annual Operating Budget and Financial Projections. Within forty-five (45) days after the end of each fiscal year of Borrower, and within ten (10) days of any updates or amendments thereto approved by Borrower's Board, (i) annual operating budgets (including income statements and cash flow statements, by month) for the then-current fiscal year of Borrower, and (ii) annual financial projections for the then-current fiscal year (on a quarterly basis), as approved by the Board in the case of the budget and as reviewed by the Board in the case of projections, together with any related business forecasts used in the preparation of such annual financial projections;

(d) Quarterly and Annual Financial Statements. (i) As soon as available, and in any event within forty-five (45) days after the end of the first three fiscal quarters of Borrower, company prepared consolidated balance sheet, cash flow statement, and income statement covering Borrower's and its Subsidiaries' operations for

such quarter certified by a Responsible Officer (which certification shall be satisfied by the officer certifications included in Borrower's Quarterly Report on Form 10-Q) and consistent with those filed with the SEC (the "**Quarterly Financial Statements**"); and (ii) as soon as available, but no later than ninety (90) days after the last day of Borrower's fiscal year, audited consolidated financial statements of Borrower and its Subsidiaries prepared in accordance with GAAP;

(e) SEC Filings. Within five (5) days of filing, notification of the filing and copies of all periodic and other reports, proxy statements and other materials filed by Borrower and/or any of its Subsidiaries or any Guarantor with the SEC, any Governmental Authority succeeding to any or all of the functions of the SEC, or distributed to its shareholders generally, as the case may be. Documents required to be delivered pursuant to the terms of this Agreement (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower or any of its Subsidiaries posts such documents, or provides a link thereto, on Borrower's or any of its Subsidiaries' website on the internet at Borrower's or any of its Subsidiaries' website address;

(f) Security Holder and Subordinated Debt Holder Reports. Within five (5) days of delivery, copies of all material statements, reports and notices made available to Borrower's security holders or to any holders of Subordinated Debt (solely in their capacities as security holders or holders of Subordinated Debt and not in any other role);

(g) Beneficial Ownership Information. Prompt written notice of any changes to the beneficial ownership information set out in Section 14 of the Perfection Certificate. Borrower understands and acknowledges that Bank relies on such true, accurate and up-to-date beneficial ownership information to meet Bank's regulatory obligations to obtain, verify and record information about the beneficial owners of its legal entity customers;

(h) Legal Action Notice. Prompt written notice of any legal actions, investigations or proceedings pending or threatened in writing against Borrower or any of its Subsidiaries that could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of, individually or in the aggregate, Five Hundred Thousand Dollars (\$500,000) or more;

(i) Tort Claim Notice. If Borrower shall acquire a commercial tort claim with a value in excess of One Hundred Thousand Dollars (\$100,000) individually or in the aggregate, Borrower shall promptly notify Bank in a writing signed by Borrower of the general details thereof and grant to Bank in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Bank;

(j) Government Filings. Within five (5) days after the same are sent or received, copies of all material correspondence, reports, documents and other filings by Borrower or any of its Subsidiaries with any Governmental Authority, regarding compliance with or maintenance of Governmental Approvals or Applicable Law or that could reasonably be expected to have a material effect on any of the Governmental Approvals or otherwise on the business of Borrower or any of its Subsidiaries;

(k) Registered Organization. If Borrower is not a Registered Organization as of the Effective Date but later becomes one, promptly notify Bank of such occurrence and provide Bank with Borrower's organizational identification number;

(l) Default. Prompt written notice of the occurrence of a Default or Event of Default; and

(m) Other Information. Promptly, from time to time, such other information regarding Borrower or any of its Subsidiaries or compliance with the terms of any Loan Documents as reasonably requested by Bank.

Any submission by Borrower of a Compliance Statement, or any other financial statement submitted to the Financial Statement Repository pursuant to this Section 5.3 or otherwise submitted to Bank shall be deemed to be a representation by Borrower that (i) as of the date of such Compliance Statement, or other financial statement, the

information and calculations set forth therein are true and correct in all material respects, (ii) as of the end of the compliance period set forth in such submission, Borrower is in complete compliance with all required covenants except as noted in such Compliance Statement, or other financial statement, as applicable, (iii) as of the date of such submission, no Events of Default have occurred or are continuing, (iv) all representations and warranties other than any representations or warranties that are made as of a specific date in Section 4 remain true and correct in all material respects as of the date of such submission except as noted in such Compliance Statement, or other financial statement, as applicable, (v) as of the date of such submission, Borrower and each of its Subsidiaries has timely filed all required tax returns and reports, and Borrower has timely paid all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower except as otherwise permitted pursuant to the terms of Section 4.9, and (vi) as of the date of such submission, no Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Bank.

**5.4[Intentionally Omitted].**

**5.5[Intentionally Omitted].**

**5.6Taxes; Pensions.**

(a)Timely file, and require each of its Subsidiaries to timely file (in each case, unless subject to a valid extension), all required United States federal and state income and all other material tax returns and reports and timely pay, and require each of its Subsidiaries to timely pay, all United States federal and state income taxes and all other material foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower and each of its Subsidiaries, except for deferred payment of any taxes contested pursuant to the terms of Section 4.9(a) hereof, and shall deliver to Bank, on written demand, appropriate certificates attesting to such payments, and pay, and require each of its Subsidiaries to pay, all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms.

(b)To the extent Borrower or any of its Subsidiaries defers payment of any contested taxes, Borrower and each Subsidiary shall, except as otherwise permitted under Section 4.9(a) hereof, (i) notify Bank in writing of the commencement of, and any material development in, the proceedings, and (ii) post bonds or take any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a "Permitted Lien."

**5.7Access to Collateral; Books and Records.** At reasonable times, on five (5) Business Days' notice (provided no notice is required if an Event of Default has occurred and is continuing), Bank, or its agents, shall have the right to inspect the Collateral and the right to audit and copy Borrower's Books. Such inspections and audits shall be conducted no more often than once every twelve (12) months, unless an Event of Default has occurred and is continuing, in which case such inspections and audits shall occur as often as Bank shall determine is necessary. The foregoing inspections and audits shall be conducted at Borrower's expense and the charge therefor shall be One Thousand Dollars (\$1,000) per person per day (or such higher amount as shall represent Bank's then-current standard charge for the same), plus out-of-pocket expenses. In the event Borrower and Bank schedule an audit more than eight (8) days in advance, and Borrower cancels or seeks to or reschedules the audit with less than eight (8) days written notice to Bank, then (without limiting any of Bank's rights or remedies) Borrower shall pay Bank a fee of Two Thousand Dollars (\$2,000) plus any out-of-pocket expenses incurred by Bank to compensate Bank for the anticipated costs and expenses of the cancellation or rescheduling.

**5.8Insurance.**

(a)Keep its business and the Collateral insured for risks and in amounts standard for companies in Borrower's industry and location and as Bank may reasonably request. Insurance policies shall be in a form, with financially sound and reputable insurance companies that are not Affiliates of Borrower, and in amounts that are reasonably satisfactory to Bank.

(b) All property policies shall have a lender's loss payable endorsement showing Bank as lender loss payee. All liability policies shall show, or have endorsements showing, Bank as an additional insured. Bank shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral.

(c) Ensure that proceeds payable under any property policy are, at Bank's option, payable to Bank on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to Two Hundred Fifty Thousand Dollars (\$250,000) with respect to any loss, but not exceeding Five Hundred Thousand Dollars (\$500,000) in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Bank has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Bank, be payable to Bank on account of the Obligations.

(d) At Bank's request, Borrower shall deliver certified copies of insurance policies and evidence of all premium payments. Each provider of any such insurance required under this Section 5.8 shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to Bank, that it will give Bank thirty (30) days prior written notice before any such policy or policies shall be canceled or altered in any material respect. If Borrower fails to obtain insurance as required under this Section 5.8 or to pay any amount or furnish any required proof of payment to third persons and Bank, Bank may make all or part of such payment or obtain such insurance policies required in this Section 5.8, and take any action under the policies Bank deems prudent.

#### **5.9 Accounts.**

(a) Within five (5) Business Days after the later to occur of the (i) Effective Date or (ii) the date on which Borrower opens a Securities Account with U.S. Bank National Association, which the parties intend to be subject to a Control Agreement in favor of Bank and SVB Asset Management (or, in any event, such longer period of time as is permitted by Bank, in writing, in advance), Borrower shall maintain account balances in Borrower's, any of its Subsidiaries', and any Guarantor's operating accounts, depository accounts and securities accounts at or through Bank or Bank's Affiliates representing at least [\*\*\*] of the Dollar Equivalent value of all deposit account and securities account balances of Borrower, such Subsidiary and such Guarantor at all financial institutions; provided, however, for a period of time not to exceed five (5) Business Days, Borrower, each Subsidiary, and any Guarantor may maintain up to [\*\*\*] of their cash and Cash Equivalents outside of Bank. Notwithstanding the foregoing, if at any time, the Dollar Equivalent value of all of Borrower's, any of its Subsidiaries' and any Guarantor's cash and Cash Equivalents maintained at all financial institutions is less than one hundred ten percent (110.0%) of the principal amount of the outstanding Term Loan Advances owing by Borrower to Bank, then at all times thereafter, Borrower, any of its Subsidiaries, and any Guarantor shall be required to maintain all of their operating accounts, depository accounts, securities accounts, and excess cash with Bank or Bank's Affiliates.

(b) In addition to the foregoing, Borrower, any Subsidiary of Borrower and any Guarantor, shall obtain any business credit card, any letter of credit (other than the Existing Letter of Credit) and cash management services exclusively from Bank.

(c) In addition to and without limiting the restrictions in (a), Borrower shall provide Bank five (5) days prior written notice before establishing any Collateral Account at or with any bank or financial institution other than Bank or Bank's Affiliates (and such notice shall be deemed to automatically update the disclosure in the Perfection Certificate). For each Collateral Account that Borrower at any time maintains, Borrower shall cause the applicable bank or financial institution (other than Bank) at or with which any Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Bank's Lien in such Collateral Account in accordance with the terms hereunder which Control Agreement may not be terminated without the prior written consent of Bank. The provisions of the previous sentence shall not apply to (i) deposit accounts exclusively used for payroll, payroll taxes, and other employee wage and benefit payments to or for the benefit of Borrower's employees and identified to Bank by Borrower as such; provided, however, that the funds on deposit in such deposit accounts will at no time exceed the actual payroll, payroll taxes, withholding taxes and other employee wage and benefit payments then owing for the immediately succeeding payroll



period (or greater amount to the extent required by Applicable Law), or (ii) LC Cash Collateral Account so long as the funds on deposit in such account do not at any time exceed Four Hundred Thousand Dollars (\$400,000) (collectively, "**Excluded Accounts**").

**5.10[Intentionally Omitted].**

**5.11Protection of Intellectual Property Rights.**

(a)(i) Protect, defend and maintain the validity and enforceability of Borrower's and each Subsidiary's Intellectual Property, except to the extent that such failure to do so would not reasonably be expected to have a material adverse effect on Borrower's business or operations; (ii) promptly advise Bank in writing of infringements or any other event that could reasonably be expected to materially and adversely affect the value of Borrower's and each Subsidiary's Intellectual Property; and (iii) not allow any Intellectual Property material to Borrower's or any Subsidiary's business to be abandoned, forfeited or dedicated to the public without Bank's written consent.

(b)[Intentionally Omitted].

(c)Provide written notice to Bank within ten (10) days of entering or becoming bound by any Restricted License (other than over-the-counter software that is commercially available to the public, open source software or click-wrap licenses). Borrower shall take such steps as Bank reasonably requests to obtain the consent of, or waiver by, any person whose consent or waiver is necessary for (i) any such Restricted License to be deemed "Collateral" and for Bank to have a security interest in it that might otherwise be restricted or prohibited by law or by the terms of any such Restricted License, whether now existing or entered into in the future, and (ii) Bank to have the ability in the event of a liquidation of any Collateral to dispose of such Collateral in accordance with Bank's rights and remedies under this Agreement and the other Loan Documents.

**5.12Litigation Cooperation.** From the date hereof and continuing through the termination of this Agreement, make available to Bank, without expense to Bank, Borrower and its officers, employees and agents and Borrower's books and records, to the extent that Bank may deem them reasonably necessary to prosecute or defend any third-party suit or proceeding instituted by or against Bank with respect to any Collateral or relating to Borrower.

**5.13[Intentionally Omitted].**

**5.14Formation or Acquisition of Subsidiaries.** Notwithstanding and without limiting the negative covenants contained in Sections 6.3 and 6.7 hereof, at the time that Borrower or any Guarantor forms any Subsidiary or acquires any Subsidiary after the Effective Date (including, without limitation, pursuant to a Division), Borrower and such Guarantor shall (a) cause such new Subsidiary to provide to Bank a joinder to this Agreement to become a co-borrower hereunder or a guaranty to become a Guarantor hereunder (as determined by Bank in its sole discretion), together with documentation, all in form and substance satisfactory to Bank (including being sufficient to grant Bank a first priority Lien (subject to Permitted Liens) in and to the assets of such newly formed or acquired Subsidiary), (b) provide to Bank appropriate certificates and powers and financing statements, pledging all of the direct or beneficial ownership interest in such new Subsidiary, in form and substance satisfactory to Bank; and (c) provide to Bank all other documentation in form and substance satisfactory to Bank, including one or more opinions of counsel satisfactory to Bank, which in its opinion is appropriate with respect to the execution and delivery of the applicable documentation referred to above. Any document, agreement, or instrument executed or issued pursuant to this Section 5.14 shall be a Loan Document.

**5.15Inventory; Returns.** Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower and its Account Debtors shall follow Borrower's customary practices as they exist at the Effective Date. Borrower shall promptly notify Bank of all returns, recoveries, disputes and claims that involve more than One Hundred Thousand Dollars (\$100,000).

**5.16Further Assurances.** Execute any further instruments and take such further action as Bank reasonably requests to effect the purposes of this Agreement, including, but not limited to, perfecting, protecting, and/or ensuring the priority of or continue Bank's Lien on the Collateral.

**5.17Sanctions.** (a) Not, and not permit any of its Subsidiaries to, engage in any of the activities described in Section 4.11 in the future; (b) not, and not permit any of its Subsidiaries to, become a Sanctioned Person; (c) ensure that the proceeds of the Obligations are not used to violate any Sanctions; and (d) deliver to Bank any certification or other evidence requested from time to time by Bank in its sole discretion, confirming each such Person's compliance with this Section 5.17. In addition, have implemented, and will consistently apply while this Agreement is in effect, procedures to ensure that the representations and warranties in Section 4.11 remain true and correct while this Agreement is in effect.

**5.18Post-Closing Conditions.**

(a) On or prior to the date that is thirty (30) days after the Effective Date, Borrower shall deliver to Bank evidence satisfactory to Bank demonstrating that the insurance policies and endorsements required by Section 5.8 hereof are in full force and effect, together with appropriate evidence showing lender loss payable and additional insured clauses or endorsements in favor of Bank.

(b) On or prior to the date that is forty-five (45) days after the Effective Date, Borrower shall use commercially reasonable efforts to deliver to Bank a landlord consent in form and substance satisfactory to Bank for each of Borrower's leased locations at (i) 171 Oyster Point Blvd., Suite 500, South San Francisco, CA 94080, and (ii) 33498 Central Avenue, Union City, CA 94587.

(c) On or prior to the date that is five (5) Business Days after the Effective Date, Borrower shall deliver to Bank duly executed Control Agreements with (A) Morgan Stanley, (B) JPMorgan Chase Bank, N.A., and (C) SVB Asset Management.

**6.NEGATIVE COVENANTS**

Borrower shall not do any of the following without Bank's prior written consent:

**6.1Dispositions.** Convey, sell, lease, transfer, assign, or otherwise dispose of (including, without limitation, pursuant to a Division) (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn-out, surplus or obsolete Equipment that is, in the reasonable judgment of Borrower, no longer economically practicable to maintain or useful in the ordinary course of business of Borrower; (c) consisting of Permitted Liens and Permitted Investments or Transfers permitted by Section 6.3 or Section 6.7; (d) consisting of the sale or issuance of any stock, partnership, membership, or other ownership interest or other equity securities of Borrower permitted under Section 6.2 of this Agreement; (e) consisting of Borrower's or its Subsidiaries' use or transfer of money or Cash Equivalents in a manner that is not prohibited by the terms of this Agreement or the other Loan Documents; (f) of (i) non-exclusive licenses for the use of the property of Borrower or its Subsidiaries in the ordinary course of business and (ii) certain exclusive licenses for the use of the property of Borrower or its Subsidiaries in the ordinary course of business that could not result in a legal transfer of title of the licensed property but that may be exclusive in respects other than territory and that may be exclusive as to territory only as to discrete geographical areas outside of the United States; (g) consisting of the abandonment, forfeiture or dedication to the public of any Intellectual Property that is immaterial to Borrower's business; and (h) other Transfers not otherwise permitted in clauses (a) through (g) above involving tangible assets of Borrower (but specifically excluding any Transfers of Accounts, monthly recurring revenue, annual recurring revenue or any other recurring revenue of Borrower in any factoring, sale-leaseback, future receipts purchase agreement or other similar agreement) having a fair market value of not more than Two Hundred Fifty Thousand Dollars (\$250,000) in the aggregate in any fiscal year so long as no Event of Default has occurred or would occur immediately following any such Transfer.

**6.2Changes in Business, Management, Control, or Business Locations.** (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses currently engaged in by Borrower and such

Subsidiary, as applicable, or reasonably related or incidental thereto (including the provision of manufacturing services); (b) liquidate or dissolve or permit any of its Subsidiaries to liquidate or dissolve; (c) fail to provide notice to Bank of any Key Person departing from or ceasing to be employed by Borrower within five (5) days after such Key Person's departure from Borrower; (d) permit, allow or suffer to occur any Change in Control; or (e) without at least ten (10) days prior written notice to Bank, (i) add any new offices or business locations, including warehouses (unless such new offices or business locations contain less than Five Hundred Thousand Dollars (\$500,000) in Borrower's assets or property) or deliver any portion of the Collateral valued, individually or in the aggregate, in excess of Five Hundred Thousand Dollars (\$500,000) to a bailee at a location other than to a bailee and at a location already disclosed in the Perfection Certificate, (ii) change its jurisdiction of organization, (iii) change its organizational structure or type, (iv) change its legal name, or (v) change any organizational number (if any) assigned by its jurisdiction of organization. If Borrower intends to add any new offices or business locations, including warehouses, containing in excess of Five Hundred Thousand Dollars (\$500,000) of Borrower's assets or property, then Borrower will use commercially reasonable efforts to cause the landlord of any such new offices or business locations, including warehouses, to execute and deliver a landlord consent in form and substance reasonably satisfactory to Bank. If Borrower intends to deliver any portion of the Collateral valued, individually or in the aggregate, in excess of Five Hundred Thousand Dollars (\$500,000) to a bailee, and Bank and such bailee are not already parties to a bailee agreement governing both the Collateral and the location to which Borrower intends to deliver the Collateral, then Borrower will use commercially reasonable efforts cause such bailee to execute and deliver a bailee agreement in form and substance reasonably satisfactory to Bank.

**6.3Mergers or Acquisitions.** Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the stock, partnership, membership, or other ownership interest or other equity securities or property of another Person (including, without limitation, by the formation of any Subsidiary or pursuant to a Division). Notwithstanding the foregoing, any Subsidiary may merge or consolidate into another Subsidiary or into Borrower.

**6.4Indebtedness.** Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

**6.5Encumbrance.** Create, incur, allow, or suffer to exist any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens and Transfers permitted by Section 6.1, permit any Collateral not to be subject to the first priority security interest granted herein, or enter into any agreement, document, instrument or other arrangement (except with or in favor of Bank) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower or any Subsidiary from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or any Subsidiary's Intellectual Property, except (i) as is otherwise permitted in Section 6.1 hereof and the definition of "Permitted Liens" herein, (ii) for customary restrictions on assignment, transfer and encumbrances in license agreements under which Borrower or any Subsidiary is the licensee, or (iii) for covenants with such restrictions in merger or acquisition agreements; provided that such covenants do not prohibit Borrower or any Subsidiary from granting a security interest in Borrower's or any such Subsidiary's Intellectual Property in favor of Bank; and provided further that the counter-parties to such covenants are not permitted to receive a security interest in Borrower's or any Subsidiary's Intellectual Property.

**6.6Maintenance of Collateral Accounts.** Maintain any Collateral Account except pursuant to the terms of Section 5.9(c).

**6.7Distributions; Investments.** (a) Pay any dividends or make any distribution on account of Borrower's equity securities or payment or redeem, retire or purchase any stock, partnership, membership, or other ownership interest or other equity securities of Borrower; provided that Borrower may (i) convert any of its convertible securities into other securities pursuant to the terms of such convertible securities or otherwise in exchange thereof, (ii) pay cash in lieu of the issuance of fractional shares provided that the aggregate amount of all such payments does not exceed Two Hundred Fifty Thousand Dollars (\$250,000), (iii) pay dividends solely in common stock, (iv) repurchase the stock, partnership, membership, or other ownership interest or other equity securities of former employees, directors or consultants pursuant to stock repurchase agreements so long as an Event of Default does not exist at the time of any such repurchase and would not exist after giving effect to any such repurchase, provided that the aggregate amount of all such repurchases does not exceed Two Hundred Fifty Thousand Dollars (\$250,000) per

fiscal year (or in any amount where the consideration for such repurchase is the cancellation of Indebtedness under non-cash loans to current or former employees, officers, managers, directors, or consultants relating to the purchase of capital stock of Borrower pursuant to equity purchase plans or equity compensation arrangements approved by the Board), (v) make purchases of capital stock deemed to occur in connection with the exercise of stock options or stock appreciation rights by way of cashless exercise or in connection with the satisfaction of withholding tax obligations, and (vi) make other dividends, distributions, redemptions or repurchases so long as the aggregate amount of all such purchases does not exceed Two Hundred Fifty Thousand Dollars (\$250,000); or (b) directly or indirectly make any Investment (including, without limitation, by the formation of any Subsidiary) other than Permitted Investments, or permit any of its Subsidiaries to do so other than Permitted Investments.

**6.8 Transactions with Affiliates.** Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower, except (a) for transactions that are in the ordinary course of Borrower's business, upon fair and reasonable terms that are no less favorable to Borrower than would be obtained in an arm's length transaction with a non-affiliated Person, (b) transactions between Borrower and any of its Subsidiaries which are not prohibited hereunder, (c) transactions of the type described in and permitted under Section 6.7, and (d) reasonable and customary compensation arrangements approved by the Board or a duly authorized committee thereof.

**6.9 Subordinated Debt.** Except as expressly permitted under the terms of the subordination, intercreditor, or other similar agreement to which any Subordinated Debt is subject: (a) make or permit any payment on such Subordinated Debt; or (b) amend any provision in any document relating to such Subordinated Debt which would increase the amount thereof, provide for earlier or greater principal, interest, or other payments thereon, or adversely affect the subordination thereof to Obligations owed to Bank.

**6.10 Compliance.** (a) Become required to register as an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; (b)(i) fail to meet the minimum funding requirements of ERISA, (ii) permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur, (iii) fail to comply with the Federal Fair Labor Standards Act or (iv) violate any other law or regulation, if the foregoing subclauses (i) through (iv), individually or in the aggregate, could reasonably be expected to have a material adverse effect on Borrower's business or operations, or permit any of its Subsidiaries to do so; or (c) withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

## **7. EVENTS OF DEFAULT**

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

**7.1 Payment Default.** Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day cure period shall not apply to payments due on the Term Loan Maturity Date). During the cure period, the failure to make or pay any payment specified under clause (b) hereunder is not an Event of Default (but no Credit Extension will be made during the cure period);

### **7.2 Covenant Default.**

(a) Borrower fails or neglects to perform any obligation in Section 5 (other than Sections 5.2 (Government Compliance), 5.12 (Litigation Cooperation), 5.15 (Inventory; Returns) and 5.16 (Further Assurances)) or violates any covenant in Section 6; or

(b) Borrower fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 7) under such other term, provision, condition, covenant or agreement that can be

cured, has failed to cure the default within ten (10) days after the occurrence thereof; provided, however, if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Cure periods provided under this section shall not apply, among other things, to financial covenants (if any) or any other covenants that are required to be satisfied, completed or tested by a date certain or any covenants set forth in clause (a) above;

**7.3Material Adverse Change.** A Material Adverse Change occurs;

**7.4Attachment; Levy; Restraint on Business.**

(a)(i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any Subsidiary in excess of Five Hundred Thousand Dollars (\$500,000), or (ii) a notice of lien or levy is filed against any of Borrower's or any of its Subsidiaries' assets with a value in excess of Five Hundred Thousand Dollars (\$500,000) by any Governmental Authority, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; or

(b)(i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting all or any material part of its business;

**7.5Insolvency.** (a) Borrower or any of its Subsidiaries is unable to pay its debts (including trade debts) as they become due or otherwise becomes insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and is not dismissed or stayed within thirty (30) days (but no Credit Extensions shall be made while any of the conditions described in clause (a) exist or until any Insolvency Proceeding is dismissed);

**7.6Other Agreements.** There is, under any agreement to which Borrower, any of Borrower's Subsidiaries, or any Guarantor is a party with a third party or parties, (a) any default resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount individually or in the aggregate in excess of Five Hundred Thousand Dollars (\$500,000); or (b) any breach or default by Borrower, any of Borrower's Subsidiaries, or Guarantor, the result of which could reasonably be expected to have a material adverse effect on Borrower's, any of Borrower's Subsidiaries', or any Guarantor's business or operations; provided, however, that the Event of Default under this Section 7.6 caused by the occurrence of a breach or default under such other agreement shall be cured or waived for purposes of this Agreement upon Bank receiving written notice from the party asserting such breach or default of such cure or waiver of the breach or default under such other agreement, if at the time of such cure or waiver under such other agreement (x) Bank has not declared an Event of Default under this Agreement and/or exercised any rights with respect thereto; (y) any such cure or waiver does not result in an Event of Default under any other provision of this Agreement or any Loan Document; and (z) in connection with any such cure or waiver under such other agreement, the terms of any agreement with such third party are not modified or amended in any manner which could in the good faith business judgment of Bank be materially less advantageous to Borrower.

**7.7Judgments; Penalties.** One or more fines, penalties or final judgments, orders or decrees for the payment of money in an amount, individually or in the aggregate, or litigation or other dispute resolution settlement payments by Borrower or any of its Subsidiaries, of at least Five Hundred Thousand Dollars (\$500,000) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries by any Governmental Authority, and the same are not, within ten (10) days after the acceptance, entry, assessment or issuance thereof, discharged, or after execution thereof, or stayed pending appeal, or such judgments are not discharged prior to the expiration of any such stay (provided that no Credit Extensions will be made prior to the discharge, or stay of such fine, penalty, judgment, order or decree);

**7.8 Misrepresentations.** Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Bank or to induce Bank to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made (it being agreed and acknowledged by Bank that the projections and forecasts provided by Borrower or any of its Subsidiaries in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results);

**7.9 Subordinated Debt.** If: (a) any document, instrument, or agreement evidencing any Subordinated Debt shall for any reason be revoked or invalidated or otherwise cease to be in full force and effect, or any Person (other than Bank) shall be in breach thereof or contest in any manner the validity or enforceability thereof or deny that it has any further liability or obligation thereunder; (b) a default or event of default (however defined) has occurred under any document, instrument, or agreement evidencing any Subordinated Debt, which default shall not have been cured or waived within any applicable grace period; or (c) the Obligations shall for any reason be subordinated or shall not have the priority contemplated by this Agreement or any applicable subordination or intercreditor agreement;

**7.10 Lien Priority.** There is a material impairment in the perfection or priority of Bank's security interest in the Collateral;

**7.11 Guaranty.** (a) Any guaranty of any Obligations terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any guaranty of the Obligations; (c) any circumstance described in Sections 7.3, 7.4, 7.5, 7.6, 7.7, 7.8 or 7.12 of this Agreement occurs with respect to any Guarantor, (d) the death, liquidation, winding up, or termination of existence of any Guarantor; or (e)(i) a material impairment in the perfection or priority of Bank's Lien in the collateral provided by Guarantor or in the value of such collateral or (ii) a material adverse change in the general affairs, management, results of operation, condition (financial or otherwise) or the prospect of repayment of the Obligations occurs with respect to any Guarantor; or

**7.12 Governmental Approvals.** Any Governmental Approval shall have been (a) revoked, rescinded, suspended, modified in an adverse manner or not renewed in the ordinary course for a full term or (b) subject to any decision by a Governmental Authority that designates a hearing with respect to any applications for renewal of any of such Governmental Approval or that could result in the Governmental Authority taking any of the actions described in clause (a) above, and such decision or such revocation, rescission, suspension, modification or non-renewal (i) causes, or could reasonably be expected to cause, a Material Adverse Change, or (ii) materially and adversely affects the legal qualifications of Borrower or any of its Subsidiaries to hold such Governmental Approval material to Borrower's business in any applicable jurisdiction and such revocation, rescission, suspension, modification or non-renewal could reasonably be expected to affect the status of or legal qualifications of Borrower or any of its Subsidiaries to hold any Governmental Approval in any other jurisdiction.

**7.13 Delisting.** Borrower's common stock shares are delisted from an exchange or market because of Borrower's failure to comply with continued listing standards thereof or due to a voluntary delisting which results in such shares not being listed on such exchange or market.

## **8. BANK'S RIGHTS AND REMEDIES**

**8.1 Rights and Remedies.** Upon the occurrence and during the continuance of an Event of Default, Bank may, without notice or demand, do any or all of the following:

(a) declare all Obligations immediately due and payable (but if an Event of Default described in Section 7.5 occurs all Obligations are immediately due and payable without any action by Bank);

(b) stop advancing money or extending credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Bank;

(c) demand that Borrower (i) deposit cash with Bank in an amount equal to at least (A) one hundred five percent (105.0%) of the aggregate face amount of any Letters of Credit denominated in Dollars remaining

undrawn, and (B) one hundred ten percent (110.0%) of the Dollar Equivalent of the aggregate face amount of any Letters of Credit denominated in a Foreign Currency remaining undrawn (plus, in each case, all interest, fees, and costs due or estimated by Bank to become due in connection therewith), to secure all of the Obligations relating to such Letters of Credit, as collateral security for the repayment of any future drawings under such Letters of Credit, and Borrower shall forthwith deposit and pay such amounts, and (ii) pay in advance all letter of credit fees scheduled to be paid or payable over the remaining term of any Letters of Credit;

(d) terminate any FX Contracts (it being understood and agreed that (i) Bank is not obligated to deliver the currency which Borrower has contracted to receive under any FX Contract, and Bank may cover its exposure for any FX Contracts by purchasing or selling currency in the interbank market as Bank deems appropriate; (ii) Borrower shall be liable for all losses, damages, costs, margin obligations and expenses incurred by Bank arising from Borrower's failure to satisfy its obligations under any FX Contract or the execution of any FX Contract; and (iii) Bank shall not be liable to Borrower for any gain in value of a FX Contract that Bank may obtain in covering Borrower's breach);

(e) verify the amount of, demand payment of and performance under, and collect any Accounts and General Intangibles, settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Bank considers advisable, and notify any Person owing Borrower money of Bank's security interest in such funds;

(f) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Bank requests and make it available as Bank designates. Bank may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Bank a license to enter and occupy any of its premises, without charge, to exercise any of Bank's rights or remedies pursuant to this Agreement;

(g) apply to the Obligations any (i) balances and deposits of Borrower it holds, or (ii) amount held by Bank owing to or for the credit or the account of Borrower;

(h) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral. For use solely upon the occurrence and during the continuation of an Event of Default, Bank is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's labels, Patents, Copyrights, mask works, rights of use of any name, trade secrets, trade names, Trademarks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Bank's exercise of its rights under this Section 8.1, Borrower's rights under all licenses and all franchise agreements inure to Bank's benefit;

(i) place a "hold" on any account maintained with Bank and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(j) demand and receive possession of Borrower's Books; and

(k) exercise all rights and remedies available to Bank under the Loan Documents or at law or equity, including all remedies provided under the Code or any Applicable Law (including disposal of the Collateral pursuant to the terms thereof).

**8.2 Power of Attorney.** Borrower hereby irrevocably appoints Bank as its true and lawful attorney-in-fact, (a) exercisable upon the occurrence and during the continuance of an Event of Default, to: (i) endorse Borrower's name on any checks, payment instruments, or other forms of payment or security; (ii) sign Borrower's name on any invoice or bill of lading for any Account or drafts against Account Debtors; (iii) demand, collect, sue, and give releases to any Account Debtor for monies due, settle and adjust disputes and claims about the Accounts directly with Account Debtors, and compromise, prosecute, or defend any action, claim, case, or proceeding about any Collateral (including filing a claim or voting a claim in any bankruptcy case in Bank's or Borrower's name, as Bank chooses); (iv) make,

settle, and adjust all claims under Borrower's insurance policies; (v) pay, contest or settle any Lien, charge, encumbrance, security interest, or other claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (vi) transfer the Collateral into the name of Bank or a third party as the Code permits; and (vii) receive, open and dispose of mail addressed to Borrower; and (b) regardless of whether an Event of Default has occurred, to (i) notify all Account Debtors to pay Bank directly; and (ii) sign Borrower's name on any documents necessary to perfect or continue the perfection of Bank's security interest in the Collateral. Bank's foregoing appointment as Borrower's attorney in fact, and all of Bank's rights and powers, coupled with an interest, are irrevocable until such time as all Obligations (other than inchoate indemnity obligations) have been satisfied in full, Bank is under no further obligation to make Credit Extensions and the Loan Documents have been terminated. Bank shall not incur any liability in connection with or arising from the exercise of such power of attorney and shall have no obligation to exercise any of the foregoing rights and remedies.

**8.3Protective Payments.** If Borrower fails to obtain the insurance called for by Section 5.8 or fails to pay any premium thereon or fails to pay any other amount which Borrower is obligated to pay under this Agreement or any other Loan Document or which may be required to preserve the Collateral, Bank may obtain such insurance or make such payment, and all amounts so paid by Bank are Bank Expenses and immediately due and payable, bearing interest at the then highest rate applicable to the Obligations, and secured by the Collateral. Bank will make reasonable efforts to provide Borrower with notice of Bank obtaining such insurance at the time it is obtained or within a reasonable time thereafter. No payments by Bank are deemed an agreement to make similar payments in the future or Bank's waiver of any Event of Default.

**8.4Application of Payments and Proceeds.** Bank may apply any funds in its possession, whether from Borrower account balances, payments, proceeds realized as the result of any collection of Accounts or other disposition of the Collateral, or otherwise, to the Obligations in such order as Bank shall determine in its sole discretion. Any surplus shall be paid to Borrower or other Persons legally entitled thereto; Borrower shall remain liable to Bank for any deficiency. If Bank, in its commercially reasonable discretion, directly or indirectly, enters into a deferred payment or other credit transaction with any purchaser at any sale of Collateral, Bank shall have the option, exercisable at any time, of either reducing the Obligations by the principal amount of the purchase price or deferring the reduction of the Obligations until the actual receipt by Bank of cash therefor.

**8.5Bank's Liability for Collateral.** Bank's sole duty with respect to the custody, safekeeping and physical preservation of the Collateral in its possession or under its control, under Section 9-207 of the Code or otherwise, shall be to deal with it in the same manner as Bank deals with its own property consisting of similar instruments or interests. Borrower bears all risk of loss, damage or destruction of the Collateral.

**8.6No Waiver; Remedies Cumulative.** Bank's failure, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Bank thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by the party granting the waiver and then is only effective for the specific instance and purpose for which it is given. Bank's rights and remedies under this Agreement and the other Loan Documents are cumulative. Bank has all rights and remedies provided under the Code, by law, or in equity. Bank's exercise of one right or remedy is not an election and shall not preclude Bank from exercising any other remedy under this Agreement or other remedy available at law or in equity, and Bank's waiver of any Event of Default is not a continuing waiver. Bank's delay in exercising any remedy is not a waiver, election, or acquiescence.

**8.7Demand Waiver.** Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Bank on which Borrower is liable.

## **9.NOTICES**

All notices, consents, requests, approvals, demands, or other communication by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by electronic mail; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when



delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address or email address indicated below; provided that, for clause (b), if such notice, consent, request, approval, demand or other communication is not sent during the normal business hours of the recipient, it shall be deemed to have been sent at the opening of business on the next Business Day of the recipient. Bank or Borrower may change its mailing or electronic mail address by giving the other party written notice thereof in accordance with the terms of this Section 9.

If to Borrower: Tenaya Therapeutics, Inc.  
171 Oyster Point Blvd., Suite 500  
South San Francisco, CA 94080  
Attn: [\*\*\*]  
Email: [\*\*\*]  
Website URL: <https://www.tenayatherapeutics.com/>

with a copy to (which shall not constitute notice):

Wilson Sonsini Goodrich & Rosati, P.C.  
650 Page Mill Road  
Palo Alto, CA 94304  
Attn: [\*\*\*]

Email: [\*\*\*]

If to Bank: Silicon Valley Bank, a Division of First-Citizens Bank & Trust Company  
222 2nd Street, Floors 17-20  
San Francisco, CA 94105  
Attn: [\*\*\*]  
Email: [\*\*\*]

with a copy to (which shall not constitute notice):

DLA Piper LLP (US)  
4365 Executive Drive, Suite 1100  
San Diego, CA 92121  
Attn: [\*\*\*]  
Email: [\*\*\*]

#### **10.CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER; JUDICIAL REFERENCE**

Except as otherwise expressly provided in any of the Loan Documents, California law governs the Loan Documents without regard to principles of conflicts of law that would require the application of the laws of another jurisdiction. Borrower and Bank each irrevocably and unconditionally submit to the exclusive jurisdiction of the State and Federal courts in San Francisco, California; provided, however, nothing in this Agreement shall be deemed to operate to preclude Bank from bringing suit or taking other legal action in any other jurisdiction with respect to the Loan Documents or to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of Bank. Borrower expressly, irrevocably and unconditionally submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby irrevocably and unconditionally waives, to the fullest extent permitted by Applicable Law, any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby irrevocably and unconditionally consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 9 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

**TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER AND BANK EACH WAIVES ITS RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR THE PARTIES HERETO TO ENTER INTO THIS AGREEMENT. EACH PARTY HERETO HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.**

WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES' AGREEMENT TO WAIVE THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY, if the above waiver of the right to a trial by jury is not enforceable, the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties (or, if they cannot agree, by the Presiding Judge of the San Francisco County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a jury, in San Francisco County, California; and the parties hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure Sections 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and permanent injunctions and appointing receivers. All such proceedings shall be closed to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the San Francisco County, California Superior Court for such relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings. The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The private judge shall oversee discovery and may enforce all discovery rules and orders applicable to judicial proceedings in the same manner as a trial court judge. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to California Code of Civil Procedure Section 644(a). Nothing in this paragraph shall limit the right of any party at any time to exercise self-help remedies, foreclose against collateral, or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this paragraph.

This Section 10 shall survive the termination of this Agreement and the repayment of all Obligations.

## **11. GENERAL PROVISIONS**

**11.1 Termination Prior to Maturity Date; Survival.** All covenants, representations and warranties made in this Agreement shall continue in full force until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations) have been satisfied. So long as Borrower has satisfied the Obligations (other than inchoate indemnity obligations, and any other obligations which, by their terms, are to survive the termination of this Agreement and the repayment of all Obligations, and any Obligations under Bank Services Agreements that are cash collateralized in accordance with Section 3.3 of this Agreement), this Agreement (including any unused commitments for Term Loan Advances) may be terminated prior to the Term Loan Maturity Date by Borrower, effective three (3) Business Days after written notice of termination is given to Bank (which notice may be conditioned upon the consummation of a financing or other events and may be revoked by Borrower if such condition has not or will not occur by the proposed termination date). Those obligations that are expressly specified in this Agreement as surviving this Agreement's termination and the repayment of all Obligations shall continue to survive notwithstanding this Agreement's termination and the repayment of all Obligations.

**11.2 Successors and Assigns.** This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not assign or transfer this Agreement or any rights or obligations under it without Bank's prior written consent (which may be granted or withheld in Bank's sole discretion) and any other attempted assignment or transfer by Borrower shall be null and void. Bank has the right, without the consent of or notice to Borrower, to sell, transfer, assign, negotiate, or grant participation in all or any part of, or any interest in, Bank's obligations, rights, and benefits under this Agreement and the other Loan Documents (other than the Warrant, as to which assignment, transfer and other such actions are governed by the terms thereof).

Bank, acting solely for this purpose as a non-fiduciary agent of Borrower, shall maintain a register for the recordation of the names and addresses of the applicable lenders hereunder, and the applicable commitment(s) of, and principal amount (and stated interest) of the applicable loans owing to, each lender pursuant to the terms hereof from time to time (the "**Register**"). The entries in the Register shall be conclusive absent manifest error, and Borrower, Bank and the other lenders hereunder shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a lender hereunder for all purposes of this Agreement and the other Loan Documents. The Register shall be available for inspection by Borrower and any lender hereunder, at any reasonable time and from time to time upon reasonable prior notice. Bank and each other lender hereunder that sells a participation in any Term Loan Advance or commitment, acting solely for this purpose as a non-fiduciary agent of Borrower, shall maintain a register on which it enters the name and address of each participant and the principal amounts (and stated interest) of each participant's interest in the applicable commitments or other Obligations under the Loan Documents (the "**Participant Register**"); provided that neither Bank nor any other lender hereunder shall have any obligation to disclose all or any portion of the Participant Register (including the identity of any participant or any information relating to a participant's interest in any commitments, Letters of Credit or its other Obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, Term Loan Advance, Letter of Credit or other Obligation is in registered form under Section 5f.103-1(c) of the United States Treasury Regulations. The entries in the Participant Register shall be conclusive absent manifest error, and such lender hereunder shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement and the other Loan Documents notwithstanding notice to the contrary.

### **11.3 Indemnification; Damage Waiver, etc.**

(a) General Indemnification. Borrower shall indemnify, defend and hold Bank and its Affiliates and the partners, directors, officers, employees, agents, trustees, administrators, managers, advisors and representatives of Bank and its Affiliates (each, an "**Indemnified Person**") harmless against: all losses, claims, damages, liabilities and related expenses (including Bank Expenses and the reasonable fees, charges and disbursements of any counsel for any Indemnified Person) (collectively, "**Claims**") arising out of, in connection with, or as a result of (i) the execution or delivery of this Agreement, any other Loan Document or any agreement or instrument contemplated hereby or thereby, the performance by the parties hereto of their respective obligations hereunder or thereunder or the consummation of the transactions contemplated hereby or thereby, (ii) any Credit Extension or the use or proposed use of the proceeds therefrom, (iii) any actual or alleged presence or release of hazardous materials on or from any property owned or operated by Borrower or any of its Subsidiaries, or any environmental liability related in any way to Borrower or any of its Subsidiaries, or (iv) any actual or prospective claim, litigation, investigation or proceeding relating to any of the foregoing, whether based on contract, tort or any other theory, whether brought by a third party or by Borrower, Borrower's equity holders, affiliates, creditors or any other person, and regardless of whether any Indemnified Person is a party thereto; provided that, such indemnity shall not, as to any Indemnified Person, be available to the extent that such losses, claims, damages, liabilities or related expenses are determined by a court of competent jurisdiction by final and nonappealable judgment to have resulted from the gross negligence or willful misconduct of such Indemnified Person. All amounts due under this Section 11.3 shall be payable promptly after demand therefor. Notwithstanding anything to contrary given in this Agreement, this Section 11.3(a) shall not apply with respect to Taxes other than any Taxes that represent losses, claims, damages, etc. arising from any non-Tax claim.

(b) Waiver of Consequential Damages, Etc. To the fullest extent permitted by Applicable Law, Borrower shall not assert, and hereby waives, any claim against Bank and its Affiliates and the partners, directors, officers, employees, agents, trustees, administrators, managers, advisors and representatives of Bank and its Affiliates (each, a "**Protected Person**"), on any theory of liability, for special, indirect, consequential or punitive damages (as opposed to direct or actual damages) or any loss of profits arising out of, in connection with, or as a result of, this Agreement, any other Loan Document or any agreement or instrument contemplated hereby, the transactions contemplated hereby or thereby, any Credit Extension, or the use of the proceeds thereof. No Protected Person shall be liable for any damages arising from the use by unintended recipients of any information or other materials distributed by it through telecommunications, electronic or other information transmission systems in connection with this Agreement or the other Loan Documents or the transactions contemplated hereby or thereby.

This Section 11.3 shall survive the termination of this Agreement and the repayment of all Obligations until all statutes of limitation with respect to the Claims, losses, and expenses for which indemnity is given shall have run.

**11.4Time of Essence.** Time is of the essence for the performance of all Obligations in this Agreement.

**11.5Severability of Provisions.** Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

**11.6Amendments in Writing; Waiver; Integration.** No purported amendment or modification of this Agreement or any other Loan Document, or waiver, discharge or termination of any obligation under this Agreement or any other Loan Document, shall be effective unless, and only to the extent, expressly set forth in a writing signed by each party hereto; provided that a Loan Document may otherwise be amended in accordance with its terms. Without limiting the generality of the foregoing, no oral promise or statement, nor any action, inaction, delay, failure to require performance or course of conduct shall operate as, or evidence, an amendment, supplement or waiver or have any other effect on any Loan Document. Any waiver granted shall be limited to the specific circumstance expressly described in it, and shall not apply to any subsequent or other circumstance, whether similar or dissimilar, or give rise to, or evidence, any obligation or commitment to grant any further waiver. The Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of the Loan Documents merge into the Loan Documents.

**11.7Counterparts.** This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement. Delivery of an executed signature page of this Agreement by electronic mail transmission shall be effective as delivery of a manually executed counterpart hereof.

**11.8Confidentiality.** Bank agrees to maintain the confidentiality of Information (as defined below), except that Information may be disclosed (a) to Bank's Subsidiaries and Affiliates and their respective employees, directors, agents, attorneys, accountants and other professional advisors (collectively, "**Representatives**") and, together with Bank, collectively, "**Bank Entities**"; provided such Bank Entities are bound by confidentiality obligations substantially similar to those set forth in this Section; (b) to prospective transferees, assignees, credit providers or purchasers of Bank's interests under or in connection with this Agreement and their Representatives (provided, however, any such prospective transferee's, assignee's, credit provider's, purchaser's or their Representatives shall have entered into an agreement containing provisions substantially the same as those in this Section); (c) as required by law, regulation, subpoena, or other order; (d) to Bank's regulators or as otherwise required or requested in connection with Bank's examination or audit; (e) in connection with the exercise of remedies under the Loan Documents or any action or proceeding relating to this Agreement or any other Loan Document or the enforcement of rights hereunder or thereunder; and (f) to third-party service providers of Bank so long as such service providers have executed a confidentiality agreement with Bank with terms no less restrictive than those contained herein. "**Information**" means all information received from Borrower regarding Borrower or its business, in each case other than information that is either: (i) in the public domain or in Bank's possession when disclosed to Bank, or becomes part of the public domain (other than as a result of its disclosure by Bank in violation of this Agreement) after disclosure to Bank; or (ii) disclosed to Bank by a third party, if Bank does not know that the third party is prohibited from disclosing the information.

**11.9Electronic Execution of Documents.** The words "execution," "signed," "signature" and words of like import in any Loan Document shall be deemed to include electronic signatures, including any Electronic Signature as defined in the Electronic Transactions Law (2003 Revision) of the Cayman Islands (the "**Cayman Islands Electronic Signature Law**"), if applicable, or the keeping of records in electronic form, including any Electronic Record, as defined in Cayman Islands Electronic Signature Law, each of which shall be of the same legal effect, validity and enforceability as a manually executed signature or the use of a paper-based recordkeeping systems, as the case may be, to the extent and as provided for in any Applicable Law, including, without limitation, any state law based on the Uniform Electronic Transactions Act or the Cayman Islands Electronic Signature Law; provided, however, sections 8 and 19(3) of the Cayman Islands Electronic Signature Law shall not apply to this Agreement or the execution or delivery thereof.

**11.10Right of Setoff.** Borrower hereby grants to Bank a Lien and a right of setoff as security for all Obligations to Bank, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Bank or any entity under the control

of Bank (including a subsidiary of Bank) or in transit to any of them, and other obligations owing to Bank or any such entity. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Bank may setoff the same or any part thereof and apply the same to any liability or Obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE BANK TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER, ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

**11.11Captions and Section References.** The headings used in this Agreement are for convenience only and shall not affect the interpretation of this Agreement. Unless indicated otherwise, section references herein are to sections of this Agreement.

**11.12Construction of Agreement.** The parties hereto mutually acknowledge that they and their attorneys have participated in the preparation and negotiation of this Agreement. In cases of uncertainty this Agreement shall be construed without regard to which of the parties caused the uncertainty to exist.

**11.13Relationship.** The relationship of the parties to this Agreement is determined solely by the provisions of this Agreement. The parties do not intend to create any agency, partnership, joint venture, trust, fiduciary or other relationship with duties or incidents different from those of parties to an arm's-length contract.

**11.14Third Parties.** Nothing in this Agreement, whether express or implied, is intended to: (a) confer any benefits, rights or remedies under or by reason of this Agreement on any Persons other than the express parties to it and their respective permitted successors and assigns; (b) relieve or discharge the obligation or liability of any Person not an express party to this Agreement; or (c) give any Person not an express party to this Agreement any right of subrogation or action against any party to this Agreement.

**11.15Anti-Terrorism Law.** Bank hereby notifies Borrower that, pursuant to the requirements of Anti-Terrorism Law, Bank may be required to obtain, verify and record information that identifies Borrower, which information may include the name and address of Borrower and other information that will allow Bank to identify Borrower in accordance with Anti-Terrorism Law. Borrower hereby agrees to take any action necessary to enable Bank to comply with the requirements of Anti-Terrorism Law.

**11.16Online Banking Platform.** If Borrower uses Bank's online banking platform in connection with this Agreement, Borrower agrees to be bound by and comply with the applicable online banking terms and conditions and related online banking documents as in effect from time to time. The online banking terms and conditions may be provided as hyperlinks or "click-through" agreements on the website, which may be updated from time to time. Continued use of Bank's online banking platform shall constitute Borrower's acceptance of the applicable terms and conditions. Borrower is solely responsible for any of Borrower's employees' or agents' compliance with the online banking terms and conditions and shall ensure that (a) all persons utilizing Bank's online banking platform in connection with this Agreement, including the Administrator and other users added by them, have all relevant authority to perform the specified roles and functions on Borrower's behalf, and (b) any use of Bank's online banking platform in connection with this Agreement complies with the terms of this Agreement. Bank shall be entitled to assume the authenticity, accuracy and completeness of any information, instruction or request for a Credit Extension submitted via Bank's online banking platform and to further assume that any submissions or requests made via Bank's online banking platform have been duly authorized by an Administrator and are otherwise in accordance with the terms of this Agreement.

## **12.ACCOUNTING TERMS AND OTHER DEFINITIONS**

### **12.1Accounting and Other Terms.**

(a) Accounting terms not defined in this Agreement shall be construed following GAAP. Calculations and determinations must be made following GAAP (except for with respect to unaudited financial statements for the absence of footnotes and subject to year-end audit adjustments), provided that if at any time any

change in GAAP would affect the computation of any financial ratio or requirement set forth in any Loan Document, and either Borrower or Bank shall so request, Borrower and Bank shall negotiate in good faith to amend such ratio or requirement to preserve the original intent thereof in light of such change in GAAP; provided, further, that, until so amended, (i) such ratio or requirement shall continue to be computed in accordance with GAAP prior to such change therein and (ii) Borrower shall provide Bank financial statements and other documents required under this Agreement or as reasonably requested hereunder setting forth a reconciliation between calculations of such ratio or requirement made before and after giving effect to such change in GAAP; provided, further, that (x) all obligations of any Person that are or would have been treated as operating leases for purposes of GAAP prior to the issuance by the Financial Accounting Standards Board on February 25, 2016 of an Accounting Standards Update No. 2016-02, Leases (Topic 842) (the "ASU") shall continue to be accounted for as operating leases for purposes of all financial definitions, calculations and covenants (other than the preparation and delivery of financial statements in accordance with GAAP) for purpose of this Agreement (whether or not such operating lease obligations were in effect on such date) notwithstanding the fact that such obligations are required in accordance with the ASU (on a prospective or retroactive basis or otherwise) to be treated as capital lease obligations in accordance with GAAP.

(b) As used in the Loan Documents: (i) the words "shall" or "will" are mandatory, the word "may" is permissive, the word "or" is not exclusive, the words "includes" and "including" are not limiting, the singular includes the plural, and numbers denoting amounts that are set off in brackets are negative; (ii) the term "continuing" in the context of an Event of Default means that the Event of Default has not been remedied (if capable of being remedied) or waived; and (iii) whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of any Responsible Officer.

**12.2 Definitions.** Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in this Section 12.2. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. As used in this Agreement, the following capitalized terms have the following meanings:

"**Account**" is, as to any Person, any "account" of such Person as "account" is defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to such Person.

"**Account Debtor**" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

"**Administrator**" is an individual that is named:

(a) as an "Administrator" or similar role in the online banking enrollment form or related documents completed by Borrower with the authority to determine who will be authorized to use Bank's online banking platform on behalf of Borrower in connection with this Agreement; and

(b) as an Authorized Signer of Borrower in an approval by the Board.

"**Affiliate**" is, with respect to any Person, each other Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.

"**Agreement**" is defined in the preamble hereof.

"**Anti-Terrorism Law**" means any law relating to terrorism or money-laundering, including Executive Order No. 13224 and the USA Patriot Act.

**"Applicable Law"** means all applicable provisions of constitutions, laws, statutes, ordinances, rules, treaties, regulations, permits, licenses, approvals, interpretations and orders of courts or Governmental Authorities and all orders and decrees of all courts and arbitrators, including the Corporate Transparency Act.

**"Authorized Signer"** means any individual listed in Borrower's Borrowing Resolution who is authorized to execute the Loan Documents, including making (and executing if applicable) any Credit Extension request, on behalf of Borrower.

**"Bank"** is defined in the preamble hereof.

**"Bank Entities"** is defined in Section 11.8.

**"Bank Expenses"** are all audit fees, costs and reasonable expenses (including reasonable, out-of-pocket and documented attorneys' fees and expenses) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred with respect to Borrower or any Guarantor.

**"Bank Services"** are any products, credit services, and/or financial accommodations previously, now, or hereafter provided to Borrower or any of its Subsidiaries by Bank or any Bank Affiliate, including, without limitation, any letters of credit, cash management services (including, without limitation, merchant services, direct deposit of payroll, business credit cards, and check cashing services), interest rate swap arrangements, and foreign exchange services as any such products or services may be identified in Bank's various agreements related thereto (each, a **"Bank Services Agreement"**).

**"Bank Services Agreement"** is defined in the definition of Bank Services.

**"Board"** is Borrower's board of directors or equivalent governing body.

**"Borrower"** is set forth in the first paragraph of this Agreement.

**"Borrower's Books"** are all Borrower's books and records including ledgers, federal and state tax returns, records regarding Borrower's assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

**"Borrowing Resolutions"** are, with respect to any Person, those resolutions adopted by such Person's board of directors (and, if required under the terms of such Person's Operating Documents, stockholders) and delivered by such Person to Bank approving the Loan Documents to which such Person is a party and the transactions contemplated thereby, together with a certificate executed by its secretary on behalf of such Person certifying (a) such Person has the authority to execute, deliver, and perform its obligations under each of the Loan Documents to which it is a party, (b) that set forth as a part of or attached as an exhibit to such certificate is a true, correct, and complete copy of the resolutions then in full force and effect authorizing and ratifying the execution, delivery, and performance by such Person of the Loan Documents to which it is a party, (c) the name(s) of the Person(s) authorized to execute the Loan Documents, including making (and executing if applicable) any Credit Extension request, on behalf of such Person, together with a sample of the true signature(s) of such Person(s), and (d) that Bank may conclusively rely on such certificate unless and until such Person shall have delivered to Bank a further certificate canceling or amending such prior certificate.

**"Business Day"** is a day other than a Saturday, Sunday or other day on which commercial banks in the State of California are authorized or required by law to close.

**"Cash Equivalents"** are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc.; (c) Bank's certificates of deposit issued

maturing no more than one (1) year after issue; and (d) money market funds at least ninety-five percent (95.0%) of the assets of which constitute Cash Equivalents of the kinds described in clauses (a) through (c) of this definition.

**"Cayman Islands Electronic Signature Law"** is defined in Section 11.9.

**"Change in Control"** means (a) at any time, any "person" or "group" (as such terms are used in Sections 13(d) and 14(d) of the Exchange Act), shall become, or obtain rights (whether by means of warrants, options or otherwise) to become, the "beneficial owner" (as defined in Rules 13(d)-3 and 13(d)-5 under the Exchange Act), directly or indirectly, of thirty-five percent (35.0%) or more of the ordinary voting power for the election of directors, partners, managers and members, as applicable, of Borrower (determined on a fully diluted basis) other than by the sale of Borrower's equity securities in a public offering or the sale of Borrower's equity securities to venture capital or private equity investors so long as Borrower identifies to Bank the venture capital or private equity investors at least seven (7) Business Days prior to the closing of the transaction and provides to Bank a description of the material terms of the transaction; (b) during any period of twelve (12) consecutive months, a majority of the members of the Board of Borrower cease to be composed of individuals (i) who were members of that board or equivalent governing body on the first (1st) day of such period, (ii) whose election or nomination to that board or equivalent governing body was approved by individuals referred to in clause (i) above constituting at the time of such election or nomination at least a majority of that board or equivalent governing body or (iii) whose election or nomination to that board or other equivalent governing body was approved by individuals referred to in clauses (i) and (ii) above constituting at the time of such election or nomination at least a majority of that board or equivalent governing body; or (c) at any time, Borrower shall cease to own and control, of record and beneficially, directly or indirectly, one hundred percent (100.0%) of each class of outstanding stock, partnership, membership, or other ownership interest or other equity securities of each Subsidiary of Borrower (other than director's qualifying shares and other similar shares as required by Applicable Law) free and clear of all Liens (except Permitted Liens).

**"Change in Law"** means the occurrence, after the Effective Date, of: (a) the adoption or taking effect of any law, rule, regulation or treaty; (b) any change in Applicable Law or in the administration, interpretation, implementation or application thereof by any Governmental Authority; or (c) the making or issuance of any request, rule, guideline or directive (whether or not having the force of law) by any Governmental Authority; provided that, notwithstanding anything herein to the contrary, (i) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (ii) all requests, rules, guidelines or directives promulgated by Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall in each case be deemed to be a "Change in Law", regardless of the date enacted, adopted or issued.

**"Claims"** is defined in Section 11.3.

**"Code"** is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of California; provided that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided, further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Bank's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of California, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

**"Collateral"** consists of all of Borrower's right, title and interest in and to the following personal property:

(a)(i) all goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as provided below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts, certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, securities accounts, securities entitlements and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever



located; and (ii) all Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

(b) Notwithstanding the foregoing, the Collateral does not include (i) any interest of Borrower as a lessee or sublessee under a real property lease; (ii) rights held under a license that are not assignable by their terms without the consent of the licensor thereof (but only to the extent such restriction on assignment is enforceable under applicable law); provided that upon the termination, lapsing or expiration of any such prohibition, such license shall automatically be subject to the security interest granted in favor of Bank hereunder and become part of the "Collateral"; (iii) any Excluded Account; (iv) any interest of Borrower as a lessee under an Equipment lease if Borrower is prohibited by the terms of such lease from granting a security interest in such lease or under which such an assignment or Lien would cause a default to occur under such lease; provided, however, that upon termination of such prohibition, such interest shall immediately become Collateral without any action by Borrower or Bank; and (v) any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Bank's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property.

(c) Pursuant to the terms of a certain negative pledge arrangement with Bank as set forth in this Agreement, Borrower has agreed not to encumber any of its Intellectual Property without Bank's prior written consent.

**"Collateral Account"** is any Deposit Account, Securities Account, or Commodity Account.

**"Commodity Account"** is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

**"Compliance Statement"** is that certain statement in the form attached hereto as Exhibit A.

**"Connection Income Taxes"** means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

**"Contingent Obligation"** is, for any Person, any direct or indirect liability of that Person for (a) any direct or indirect guaranty by such Person of any indebtedness, lease, dividend, letter of credit, credit card or other obligation of another Person, (b) any other obligation of another Person endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (c) any obligations for undrawn letters of credit for the account of that Person; and (d) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

**"Control Agreement"** is any control agreement entered into among the depository institution at which Borrower maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower maintains a Securities Account or a Commodity Account, Borrower, and Bank pursuant to which Bank obtains control (within the meaning of the Code) over such Deposit Account, Securities Account, or Commodity Account.

**"Copyrights"** are any and all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

**"Credit Extension"** is any Letter of Credit, amount utilized for cash management services, Term Loan Advance, or any other extension of credit by Bank for Borrower's benefit.

**"Currency"** is coined money and such other banknotes or other paper money as are authorized by law and circulate as a medium of exchange.

**"Default"** means any event which with notice or passage of time or both, would constitute an Event of Default.

**"Default Rate"** is defined in Section 1.8(c).

**"Deposit Account"** is any **"deposit account"** as defined in the Code with such additions to such term as may hereafter be made.

**"Designated Deposit Account"** is the deposit account established by Borrower with Bank for purposes of receiving Credit Extensions.

**"Division"** means, in reference to any Person which is an entity, the division of such Person into two (2) or more separate Persons, with the dividing Person either continuing or terminating its existence as part of such division, including, without limitation, as contemplated under Section 18-217 of the Delaware Limited Liability Company Act for limited liability companies formed under Delaware law, Section 17-220 of the Delaware Revised Uniform Limited Partnership Act for limited partnerships formed under Delaware law, or any analogous action taken pursuant to any other Applicable Law with respect to any corporation, limited liability company, partnership or other entity.

**"Dollar Equivalent"** is, at any time, (a) with respect to any amount denominated in Dollars, such amount, and (b) with respect to any amount denominated in a Foreign Currency, the equivalent amount therefor in Dollars as determined by Bank at such time on the basis of the then-prevailing rate of exchange in San Francisco, California, for sales of the Foreign Currency for transfer to the country issuing such Foreign Currency.

**"Dollars," "dollars"** or use of the sign "\$" means only lawful money of the United States and not any other currency, regardless of whether that currency uses the "\$" sign to denote its currency or may be readily converted into lawful money of the United States.

**"Effective Date"** is set forth on Schedule I hereto.

**"Environmental Laws"** means any Applicable Law (including any permits, concessions, grants, franchises, licenses, agreements or governmental restrictions) relating to pollution or the protection of health, safety or the environment or the release of any materials into the environment (including those related to hazardous materials, air emissions, discharges to waste or public systems and health and safety matters).

**"Equipment"** is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

**"ERISA"** is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

**"Event of Default"** is defined in Section 7.

**"Exchange Act"** is the Securities Exchange Act of 1934, as amended.

**"Excluded Taxes"** means any of the following Taxes imposed on or with respect to Bank or required to be withheld or deducted from a payment to Bank, (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (i) imposed as a result of Bank being organized under the laws of, or having its principal office or its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (ii) that are Other Connection Taxes, (b) U.S. federal withholding

Taxes imposed on amounts payable to or for the account of Bank with respect to an applicable interest in a Credit Extension pursuant to a law in effect on the date on which (i) Bank acquires such interest in the Credit Extensions or (ii) Bank changes its lending office, except in each case to the extent that, pursuant to Section 1.12, amounts with respect to such Taxes were payable either to Bank's assignor immediately before Bank became a party hereto or to Bank immediately before it changed its lending office, (c) Taxes attributable to Bank's failure to comply with Section 1.12(e), (d) any withholding Taxes imposed under FATCA, and (e) Taxes (including withholding Taxes) imposed on or with respect to payments pursuant to the Warrant for which Bank is liable.

**"Existing Letter of Credit"** is that certain letter of credit existing on the Effective Date issued by JPMorgan Chase Bank, N.A. on behalf of Borrower for the benefit of HCP Oyster Point III LLC.

**"FATCA"** means Sections 1471 through 1474 of the Internal Revenue Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Internal Revenue Code and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and implementing such Sections of the Internal Revenue Code.

**"Final Payment"** is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Term Loan Maturity Date, (b) the repayment of the Term Loan Advances in full, (c) as required pursuant to Sections 1.5(c) or 1.5(d), or (d) the termination of this Agreement, in an amount equal to the aggregate original principal amount of the Term Loan Advances being repaid or prepaid made by Bank to Borrower multiplied by four percent (4.0%).

**"Financial Statement Repository"** is [\*\*\*] or such other means of collecting information approved and designated by Bank after providing notice thereof to Borrower from time to time.

**"Foreign Currency"** is the lawful money of a country other than the United States.

**"Funding Date"** is any date on which a Credit Extension is made to or for the account of Borrower which shall be a Business Day.

**"FX Contract"** is any foreign exchange contract by and between Borrower and Bank under which Borrower commits to purchase from or sell to Bank a specific amount of Foreign Currency at a set price or on a specified date.

**"GAAP"** is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession, which are applicable to the circumstances as of the date of determination.

**"General Intangibles"** is all "general intangibles" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all Intellectual Property, claims, income and other tax refunds, security and other deposits, payment intangibles, contract rights, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

**"Good Faith Deposit"** is defined in Section 1.9(c).

**"Governmental Approval"** is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority, including, without limitation, Healthcare Permits.

**"Governmental Authority"** is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

**"Guarantor"** is any Person providing a Guaranty in favor of Bank.

**"Guaranty"** is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

**"Healthcare Laws"** means all applicable laws relating to the operation or management of hospitalist practices, the provision of hospitalist services, proper billing and collection practices relating to the payment for healthcare services, insurance law (including law related to payment for "no-fault" claims) and workers compensation law as they relate to the provision of, and billing and payment for, healthcare services, patient healthcare, patient healthcare information, patient abuse, the quality and adequacy of rehabilitative care, rate setting, equipment, personnel, operating policies, fee splitting, including, without limitation, (a) all federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)), the Stark Law (42 U.S.C. §1395nn), the civil False Claims Act (31 U.S.C. §3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)), the exclusion laws (42 U.S.C. § 1320a-7); (b) the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009; (c) the Medicare Regulations and the Medicaid Program (Title XIX of the Social Security Act); (d) quality, safety and accreditation standards and requirements of all applicable state laws or regulatory bodies; (e) all laws, policies, procedures, requirements and regulations pursuant to which Healthcare Permits are issued; (f) any laws, regulations or administrative guidance with respect to fee splitting by healthcare professionals and the corporate practice of medicine in any jurisdiction in which any Borrower or any Guarantor operates; and (g) any and all comparable state or local laws and other applicable health care laws, regulations, manual provisions, policies and administrative guidance, each of (a) through (g) as may be amended from time to time and the regulations promulgated pursuant to each such law.

**"Healthcare Permit"** means, with respect to any Person, a permit issued or required under Healthcare Laws applicable to the business of Borrower or any Guarantor, or necessary in the possession, ownership, warehousing, marketing, promoting, sale, labeling, furnishing, distribution or delivery of goods or services under Healthcare Laws applicable to the business of Borrower or any Guarantor.

**"HIPAA"** means, collectively, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic Clinical Health (HITECH) Act and the implementing regulations thereto.

**"Indebtedness"** is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds, letters of credit and credit cards, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, (d) Contingent Obligations, and (e) other short- and long-term obligations under debt agreements, lines of credit and extensions of credit.

**"Indemnified Person"** is defined in [Section 11.3](#).

**"Indemnified Taxes"** means (a) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of Borrower under any Loan Document and (b) to the extent not otherwise described in clause (a), Other Taxes.

**"Information"** is defined in [Section 11.8](#).

**"Insolvency Proceeding"** is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, receivership or other relief.

**"Intellectual Property"** means, with respect to any Person, all of such Person's right, title, and interest in and to the following:

- (a) its Copyrights, Trademarks and Patents;
- (b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how and operating manuals;
- (c) any and all source code;
- (d) any and all design rights which may be available to such Person;
- (e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and
- (f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

**"Interest-Only Extension Milestone 1"** means [\*\*\*].

**"Interest-Only Extension Milestone 2"** means [\*\*\*].

**"Interest-Only Period"** is set forth on Schedule I hereto.

**"Internal Revenue Code"** means the U.S. Internal Revenue Code of 1986, and the rules and regulations promulgated thereunder, each as amended or modified from time to time.

**"Inventory"** is all **"inventory"** as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of Borrower's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

**"Investment"** is any beneficial ownership interest in any Person (including stock, partnership, membership, or other ownership interest or other equity securities), and any loan, advance or capital contribution to any Person.

**"Key Person"** is Borrower's Chief Executive Officer, who is Faraz Ali, as of the Effective Date.

**"LC Cash Collateral Account"** means [\*\*\*] securing the Existing Letter of Credit.

**"Letter of Credit"** is a standby or commercial letter of credit issued by Bank upon request of Borrower based upon an application, guarantee, indemnity, or similar agreement.

**"Lien"** is a claim, mortgage, deed of trust, levy, attachment, charge, pledge, hypothecation, security interest or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

**"Loan Documents"** are, collectively, this Agreement and any schedules, exhibits, certificates, notices, and any other documents related to this Agreement, the Perfection Certificate, the Warrant, any Control Agreement, any Bank Services Agreement, any subordination agreement in respect of Subordinated Debt, any note, or notes or guaranties executed by Borrower or any Guarantor pursuant to this Agreement, landlord waivers and consents pursuant to this Agreement, bailee waivers and consents pursuant to this Agreement, and any other present or future agreement by Borrower and/or any Guarantor with or for the benefit of Bank in connection with this Agreement or Bank Services, all as amended, restated, or otherwise modified in accordance with the terms thereof.

**"Material Adverse Change"** is (a) a material impairment in the perfection or priority of Bank's Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations, or condition (financial or otherwise) of Borrower; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

**"Obligations"** are Borrower's obligations to pay when due any debts, principal, interest, fees, Bank Expenses, the Prepayment Fee, the Final Payment, and other amounts Borrower owes Bank now or later, whether under this Agreement, the other Loan Documents (other than the Warrant), or otherwise, including, without limitation, all obligations relating to Bank Services and interest accruing after Insolvency Proceedings begin and debts, liabilities, or obligations of Borrower assigned to Bank, and to perform Borrower's duties under the Loan Documents (other than the Warrant).

**"OFAC"** is the Office of Foreign Assets Control of the United States Department of the Treasury and any successor thereto.

**"Operating Documents"** are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership or limited partnership, its partnership agreement or limited partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

**"Other Connection Taxes"** means, with respect to Bank, Taxes imposed as a result of a present or former connection between Bank and the jurisdiction imposing such Tax (other than connections arising from Bank having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Credit Extension or Loan Document).

**"Other Taxes"** means all present or future stamp, court, documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment.

**"Patents"** means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

**"Payment/Advance Form"** is that certain form in the form attached hereto as Exhibit B.

**"Payment Date"** is set forth on Schedule I hereto.

**"Perfection Certificate"** is the Perfection Certificate delivered by Borrower in connection with this Agreement, as amended or supplemented from time to time.

**"Permitted Indebtedness"** is:

- (g) Borrower's Indebtedness to Bank under this Agreement and the other Loan Documents;
- (h) Indebtedness existing on the Effective Date which is shown on the Perfection Certificate;
- (i) Subordinated Debt;
- (j) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;
- (k) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business;

(l)Indebtedness secured by Liens permitted under clauses (a) and (c) of the definition of "Permitted Liens" hereunder;

(m)Indebtedness owing in connection with the Existing Letter of Credit, provided that the aggregate amount of such Indebtedness does not exceed Four Hundred Thousand Dollars (\$400,000) at any time;

(n)other unsecured Indebtedness not otherwise permitted by Section 6.4 in an aggregate principal amount at any time outstanding not to exceed Two Hundred Fifty Thousand Dollars (\$250,000);

(o)Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business;

(p)Indebtedness permitted by clause (l) of the definition of Permitted Investments;

(q)Indebtedness in respect of performance, bid, appeal and surety bonds, and performance and completion guarantees and similar obligations in the ordinary course of business in an aggregate amount not to exceed One Hundred Thousand Dollars (\$100,000) at any time; and

(r)extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness under clauses (a) through (k) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose more burdensome terms upon Borrower or its Subsidiary, as the case may be.

**"Permitted Investments" are:**

(s)Investments (including, without limitation, Subsidiaries) existing on the Effective Date which are shown on the Perfection Certificate;

(t)(i) Investments consisting of Cash Equivalents and (ii) any other Investments permitted by Borrower's investment policy, as amended from time to time, provided that for purposes of this Agreement such investment policy (and any such amendment thereto) has been approved in writing by Bank (it being understood that Borrower's investment policy existing on the Effective Date is approved by Bank);

(u)Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower's business;

(v)Investments consisting of deposit accounts (but only to the extent that Borrower or any Subsidiary is permitted to maintain such accounts pursuant to Section 5.9 of this Agreement) in which Bank has a first priority perfected security interest;

(w)Investments accepted in connection with Transfers permitted by Section 6.1;

(x)Investments consisting of the creation of a Subsidiary for the purpose of consummating a merger transaction permitted by Section 6.3 of this Agreement, which is otherwise a Permitted Investment;

(y)Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers, directors, partners, managers and members relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee equity purchase plans or similar agreements approved by the Board;

(z)Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(aa) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that, this paragraph (i) shall not apply to Investments of Borrower in any Subsidiary;

(bb) Joint ventures or strategic alliances in the ordinary course of the applicable Borrower's or Subsidiary's business consisting of nonexclusive licenses of technology, the development of technology, commercialization agreements or the providing of technical support; provided that cash Investments by Borrower or any Guarantor do not exceed Two Hundred Fifty Thousand Dollars (\$250,000) in the aggregate in any fiscal year;

(cc) Investments consisting of the disposition of assets related to any of Borrower's therapy programs into another Person in exchange for equity interests in such Person and the right to receive payments of milestones and royalties so long as the aggregate value of all such assets do not exceed Two Hundred Fifty Thousand Dollars (\$250,000) in any fiscal year;

(dd)(i) Investments by Borrower or any Guarantor in Borrower or any Guarantor, (ii) Investments by a Subsidiary that is not a Borrower or Guarantor in another Subsidiary that is not a Borrower or Guarantor for the ordinary and necessary current operating expenses of such Subsidiaries in an amount not to exceed Five Hundred Thousand Dollars (\$500,000) in the aggregate in any fiscal year and (iii) Investments by Borrower or a Guarantor in any Subsidiary that is not a Borrower or Guarantor for the ordinary and necessary current operating expenses of such Subsidiaries in an amount not to exceed Five Hundred Thousand Dollars (\$500,000) in the aggregate in any fiscal year; and

(ee) other Investments not otherwise permitted herein not to exceed Two Hundred Fifty Thousand Dollars (\$250,000) in the aggregate in any fiscal year

**"Permitted Liens" are:**

(ff) Liens existing on the Effective Date which are shown on the Perfection Certificate or arising under this Agreement or the other Loan Documents;

(gg) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on Borrower's Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code;

(hh) purchase money Liens (i) on Equipment acquired or held by Borrower incurred for financing the acquisition of the Equipment securing no more than Two Hundred Fifty Thousand Dollars (\$250,000) in the aggregate amount outstanding, or (ii) existing on Equipment when acquired, if the Lien is confined to the property and improvements and the proceeds of the Equipment;

(ii) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(jj) Liens incurred in the extension, renewal or refinancing of the Indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(kk) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, nonexclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Bank a security interest therein;

(ll) non-exclusive licenses of Intellectual Property granted to third parties in the ordinary course of business;



(mm)Liens arising from attachments or judgments, orders, or decrees in circumstances not constituting an Event of Default under Sections 7.4 and 7.7;

(nn)customary Liens of any bank in connection with statutory, common law and contractual rights of setoff and recoupment with respect to any deposit account or securities account of Borrower or any Subsidiary, provided that (i) Bank has a first priority perfected security interest in such account to the extent required pursuant to Section 5.9 of this Agreement and (ii) such account is permitted to be maintained pursuant to Section 5.9 of this Agreement;

(oo)easements, rights-of-way, restrictions and other similar encumbrances affecting real property which, in the aggregate, are not substantial in amount, and which do not in any case materially detract from the value of the property subject thereto or materially interfere with the ordinary conduct of the business of the applicable Person;

(pp)Liens incurred or deposits made to secure the performance of bids, trade contracts (other than for borrowed money), leases, statutory obligations, surety and appeal bond, performance bonds and other obligations of a like nature incurred in the ordinary course of business in an aggregate amount not to exceed Two Hundred Fifty Thousand Dollars (\$250,000);

(qq)Liens in favor of customs or revenue authorities arising as a matter of law to secure payment of customs duties in connection with the importation of goods; and

(rr)Liens of JPMorgan Chase Bank, N.A. on the LC Cash Collateral Account provided that at no time shall the LC Cash Collateral Account contain assets with a value in excess of Four Hundred Thousand Dollars (\$400,000).

**"Person"** is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

**"Prepayment Fee"** is a fee due upon prepayment (whether voluntary or otherwise) of the Term Loan Advances equal to (a) three percent (3.0%) of the aggregate outstanding principal amount of the Term Loan Advances at the time of such prepayment if such prepayment occurs prior to the first (1st) anniversary of the Effective Date, (b) two percent (2.0%) of the aggregate outstanding principal amount of the Term Loan Advances at the time of such prepayment if such prepayment occurs on or at any time after the first (1st) anniversary of the Effective Date but prior to the second (2nd) anniversary of the Effective Date, and (c) one percent (1.0%) of the aggregate outstanding principal amount of the Term Loan Advances at the time of such prepayment if such prepayment occurs on or at any time after the second (2nd) anniversary of the Effective Date but prior to the Term Loan Maturity Date. Notwithstanding the foregoing, the Prepayment Fee shall be waived by Bank if the Term Loan Advances are refinanced using the proceeds of a new facility provided by Bank (the determination as to whether to provide such new facility being in Bank's sole and absolute discretion).

**"Prime Rate"** is set forth on Schedule I hereto.

**"Protected Person"** is defined in Section 11.3(b).

**"Qualified Funding Sources"** are (a) the sale of Borrower's equity securities and/or (b) upfront and nonrefundable milestone payments from licensing, collaboration, co-development agreements, or any combination thereof, on terms and conditions acceptable to Bank in its sole but reasonable discretion.

**"Registered Organization"** is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

**"Representatives"** is defined in Section 11.8.

**"Responsible Officer"** is any of the Chief Executive Officer, President, Chief Financial Officer and Controller of Borrower.

**"Restricted License"** is any material license or other material agreement with respect to which Borrower is the licensee (a) that prohibits or otherwise restricts Borrower from granting a security interest in Borrower's interest in such license or agreement or any other property, or (b) for which a default under or termination of could interfere with Bank's right to sell any Collateral.

**"Sanctioned Person"** means a Person that: (a) is listed on any Sanctions list maintained by OFAC or any similar Sanctions list maintained by any other Governmental Authority having jurisdiction over Borrower; (b) is located, organized, or resident in any country, territory, or region that is the subject or target of Sanctions; or (c) is fifty percent (50.0%) or more owned or controlled by one (1) or more Persons described in clauses (a) and (b) hereof.

**"Sanctions"** means the economic sanctions laws, regulations, embargoes or restrictive measures administered, enacted or enforced by the United States government and any of its agencies, including, without limitation, OFAC and the U.S. State Department, or any other Governmental Authority having jurisdiction over Borrower.

**"SEC"** is the Securities and Exchange Commission, any successor thereto, and any analogous Governmental Authority.

**"Securities Account"** is any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

**"Subordinated Debt"** is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all of Borrower's or any of its Subsidiaries' now or hereafter indebtedness to Bank (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Bank entered into between Bank and the other creditor), on terms acceptable to Bank.

**"Subsidiary"** is, as to any Person, a corporation, partnership, limited liability company or other entity of which shares of stock, partnership, membership, or other ownership interest or other equity securities having ordinary voting power (other than stock, partnership, membership, or other ownership interest or other equity securities having such power only by reason of the happening of a contingency) to elect a majority of the board of directors or other managers of such corporation, partnership or other entity are at the time owned, or the management of which is otherwise controlled, directly or indirectly through one or more intermediaries, or both, by such Person. Unless the context otherwise requires, each reference to a Subsidiary herein shall be a reference to a Subsidiary of Borrower.

**"Taxes"** means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

**"Term Loan Advance"** and **"Term Loan Advances"** are each defined in Section 1.5(a) of this Agreement.

**"Term Loan Amortization Date"** is set forth on Schedule I hereto.

**"Term Loan Availability Amount"** is set forth on Schedule I hereto.

**"Term Loan Maturity Date"** is set forth on Schedule I hereto.

**"Trademarks"** means, with respect to any Person, any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of such Person connected with and symbolized by such trademarks.

**"Tranche A"** is defined in Section 1.5(a) of this Agreement.

"**Tranche A Availability Amount**" is set forth on Schedule I hereto.

"**Tranche A Draw Period**" is set forth on Schedule I hereto.

"**Tranche A Term Loan Advance**" and "**Tranche A Term Loan Advances**" are each defined in Section 1.5(a) of this Agreement.

"**Tranche B**" is defined in Section 1.5(a) of this Agreement.

"**Tranche B Availability Amount**" is set forth on Schedule I hereto.

"**Tranche B Availability Milestone**" means [\*\*\*].

"**Tranche B Draw Period**" is set forth on Schedule I hereto.

"**Tranche B Term Loan Advance**" is defined in Section 1.5(a) of this Agreement.

"**Tranche C**" is defined in Section 1.5(a) of this Agreement.

"**Tranche C Availability Amount**" is set forth on Schedule I hereto.

"**Tranche C Availability Milestone**" means [\*\*\*].

"**Tranche C Draw Period**" is set forth on Schedule I hereto.

"**Tranche C Term Loan Advance**" is defined in Section 1.5(a) of this Agreement.

"**Tranche D**" defined in Section 1.5(a) of this Agreement.

"**Tranche D Availability Amount**" is set forth on Schedule I hereto.

"**Tranche D Availability Milestone**" means [\*\*\*].

"**Tranche D Draw Period**" is set forth on Schedule I hereto.

"**Tranche D Term Loan Advance**" is defined in Section 1.5(a) of this Agreement.

"**Transfer**" is defined in Section 6.1.

"**Uncommitted Accordion**" is defined in Section 1.5(a) of this Agreement.

"**USA Patriot Act**" means the "Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001" (Public Law 107-56, signed into law on October 26, 2001), as amended from time to time.

"**Warrant**" is (a) that certain Warrant to Purchase Stock dated as of the Effective Date between Borrower and Bank, together with (b) any other warrant to purchase stock issued by Borrower in favor of Bank theretofore or thereafter, in each case, as amended, modified, supplemented and/or restated from time to time.

*[Signature page follows]*

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

**BORROWER:**

**TENAYA THERAPEUTICS, INC.**

By: /s/ Leone Patterson  
Name: Leone Patterson  
Title: Chief Financial and Business Officer

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

**BANK:**

**FIRST-CITIZENS BANK & TRUST COMPANY**

By: /s/ Peter Sletteland  
Name: Peter Sletteland  
Title: Managing Director

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## **SCHEDULE I**

### **LSA PROVISIONS**

#### **LSA Section**

#### **LSA Provision**

1.5(a) – Term Loan Advances – Availability	Each Term Loan Advance must be in an amount equal to at least Five Million Dollars (\$5,000,000) or such lesser amount as remains available under the applicable tranche. After repayment, no Term Loan Advance (or any portion thereof) may be reborrowed.
1.5(b) – Term Loan Advances – Repayment	The Term Loan Advances shall be “interest-only” through the Interest-Only Period, with interest due and payable in accordance with <u>Section 1.8(a)(ii)</u> . Commencing on the Term Loan Amortization Date and continuing on each Payment Date thereafter, Borrower shall repay each Term Loan Advance in (a) thirty (30) equal monthly installments of principal, which shall reduce to twenty-four (24) equal monthly installments of principal upon the occurrence of the Interest-Only Extension Milestone 1, and which shall reduce to eighteen (18) equal monthly installments of principal upon the occurrence of the Interest-Only Extension Milestone 2, <u>plus</u> (b) monthly payments of accrued interest at the rate set forth in <u>Section 1.8(b)(ii)</u> .
1.8(a)(ii) – Interest Payments – Term Loan Advances	Interest on the principal amount of each Term Loan Advance is payable in arrears monthly (a) on each Payment Date commencing on the first Payment Date following the Funding Date of each such Term Loan Advance, (b) on the date of any prepayment, and (c) on the Term Loan Maturity Date.
1.8(b)(ii) – Interest Rate – Term Loan Advances	The outstanding principal amount of any Term Loan Advance shall accrue interest at a floating rate per annum equal to the greater of (a) eight and one half of one percent (8.50%) and (b) the Prime Rate, which interest shall be payable in accordance with <u>Section 1.8(a)(ii)</u> .
1.8(e) – Interest Computation	Interest shall be computed on the basis of the actual number of days elapsed and a 360-day year for any Credit Extension outstanding.
12.2 – “Effective Date”	“ <b>Effective Date</b> ” is August 6, 2024.
12.2 – “Interest-Only Period”	“ <b>Interest-Only Period</b> ” is the period of time commencing on the Effective Date and ending on December 31, 2025; <u>provided, however</u> , upon the occurrence of the Interest-Only Extension Milestone 1, the Interest-Only Period shall automatically, with no further action by the parties hereto, be extended through June 30, 2026; and <u>provided, further</u> , upon the occurrence of the Interest-Only Extension Milestone 2, the Interest-Only Period shall automatically, with no further action by the parties hereto, be extended through December 31, 2026.
12.2 – “Payment Date”	“ <b>Payment Date</b> ” is the first (1st) calendar day of each month.
12.2 – “Prime Rate”	“ <b>Prime Rate</b> ” is the rate of interest per annum from time to time published in the money rates section of <u>The Wall Street Journal</u> or any successor publication thereto as the “prime rate” then in effect; <u>provided that</u> , if such rate of interest, as set forth from time to time in the money rates section of <u>The Wall Street Journal</u> , becomes unavailable for any reason as determined

## LSA Section

## LSA Provision

by Bank, the "Prime Rate" shall mean the rate of interest per annum announced by Bank as its prime rate in effect at its principal office in the State of North Carolina (such Bank announced Prime Rate not being intended to be the lowest rate of interest charged by Bank in connection with extensions of credit to debtors); provided that, in the event such rate of interest is less than zero percent (0.0%) per annum, such rate shall be deemed to be zero percent (0.0%) per annum for purposes of this Agreement.

### 12.2 – "Term Loan Amortization Date"

**"Term Loan Amortization Date"** is January 1, 2026; provided, however, upon the occurrence of the Interest-Only Extension Milestone 1, the Term Loan Amortization Date shall automatically, with no further action by the parties hereto, be extended to July 1, 2026; and provided, further, upon the occurrence of the Interest-Only Extension Milestone 2, the Term Loan Amortization Date shall automatically, with no further action by the parties hereto, be extended to January 1, 2027.

### 12.2 – "Term Loan Availability Amount"

**"Term Loan Availability Amount"** is an aggregate principal amount equal to Twenty-Five Million Dollars (\$25,000,000); provided, however, if Bank, in its sole and absolute discretion, grants Borrower's request to make the Uncommitted Accordion available to Borrower, then the Term Loan Availability Amount shall be increased to Forty-Five Million Dollars (\$45,000,000).

### 12.2 – "Term Loan Maturity Date"

**"Term Loan Maturity Date"** is June 1, 2028.

### 12.2 – "Tranche A Availability Amount"

**"Tranche A Availability Amount"** is an aggregate principal amount equal to Fifteen Million Dollars (\$15,000,000).

### 12.2 – "Tranche A Draw Period"

**"Tranche A Draw Period"** is the period of time commencing on the Effective Date and ending on the earlier to occur of (a) June 30, 2025, and (b) an Event of Default.

### 12.2 – "Tranche B Availability Amount"

**"Tranche B Availability Amount"** is an aggregate principal amount equal to Five Million Dollars (\$5,000,000).

### 12.2 – "Tranche B Draw Period"

**"Tranche B Draw Period"** is the period of time commencing on the date on which Borrower achieves the Tranche B Availability Milestone and ending on the earlier to occur of (a) December 31, 2025, and (b) an Event of Default.

### 12.2 – "Tranche C Availability Amount"

**"Tranche C Availability Amount"** is an aggregate principal amount equal to Two Million Five Hundred Thousand Dollars (\$2,500,000).

### 12.2 – "Tranche C Draw Period"

**"Tranche C Draw Period"** is the period of time commencing on the date on which Borrower achieves the Tranche C Availability Milestone and ending on the earlier to occur of (a) December 31, 2025, and (b) an Event of Default.

### 12.2 – "Tranche D Availability Amount"

**"Tranche D Availability Amount"** is an aggregate principal amount equal to Two Million Five Hundred Thousand Dollars (\$2,500,000).

**LSA Section**

12.2 – “Tranche D Draw Period”

**LSA Provision**

“**Tranche D Draw Period**” is the period of time commencing on the date on which Borrower achieves the Tranche D Availability Milestone and ending on the earlier to occur of (a) December 31, 2025, and (b) an Event of Default.



**EXHIBIT A**

**COMPLIANCE STATEMENT**

TO: Silicon Valley Bank, a division of FIRST-CITIZENS BANK & TRUST COMPANY  
FROM: Tenaya Therapeutics, Inc.

Date: \_\_

Under the terms and conditions of the Loan and Security Agreement between Borrower and Bank (as amended, modified, supplemented and/or restated from time to time, the "**Agreement**"), Borrower is in complete compliance for the period ending \_\_\_\_\_ with all required covenants except as noted below. Attached are the required documents evidencing such compliance, setting forth calculations prepared in accordance with GAAP consistently applied from one period to the next except as explained in an accompanying letter or footnotes. Capitalized terms used but not otherwise defined herein shall have the meanings given them in the Agreement.

**Please indicate compliance status by circling Yes/No under "Complies" column.**

<b><u>Reporting Covenants</u></b>	<b><u>Required</u></b>	<b><u>Complies</u></b>
Bank Account Statements (for accounts outside of Bank)	Monthly within 30 days	<b>FORMCHECKBOX</b> Yes <b>FORMCHECKBOX</b> No
Quarterly Financial Statements	Quarterly within 45 days*	<b>FORMCHECKBOX</b> Yes <b>FORMCHECKBOX</b> No
Compliance Statements	Together with each monthly bank account statements and quarterly financial statements	<b>FORMCHECKBOX</b> Yes <b>FORMCHECKBOX</b> No
10-Q, 10-K and 8-K	Within 5 days after filing with SEC	<b>FORMCHECKBOX</b> Yes <b>FORMCHECKBOX</b> No
Board approved projections	FYE within 45 days and as amended/updated	<b>FORMCHECKBOX</b> Yes <b>FORMCHECKBOX</b> No

\* The Quarterly Financial Statements for Borrower's Q4 shall be delivered within 90 days

**Banking Matters**

	<b><u>Month End Balance</u></b>	<b><u>Control Agreement</u></b>
A. Amount of cash and Cash Equivalents maintained by Borrower and its Subsidiaries and Guarantors in all accounts with Bank and Bank's Affiliates* at month end.	\$_____ (A. Total)	

\* Include any amounts held in securities accounts through:

**SVB Asset Management (SAM)**

**Account Number**

A-1

_____	\$ _____	<b>FORMCHECKBOX</b> Yes
_____	\$ _____	<b>FORMCHECKBOX</b> No
_____	\$ _____	<b>FORMCHECKBOX</b> Yes
		<b>FORMCHECKBOX</b> No

B. Amount of cash and Cash Equivalents maintained by Borrower and its Subsidiaries and Guarantors in accounts with a financial institution other than Bank and Bank's Affiliates at month end. \$ \_\_\_\_\_ (B. Total)

Complete a line below for each financial institution and/or account:

<u>Financial Institution</u>	<u>Account Number</u>		
_____	_____	\$ _____	<b>FORMCHECKBOX</b> Yes
			<b>FORMCHECKBOX</b> No
_____	_____	\$ _____	<b>FORMCHECKBOX</b> Yes
			<b>FORMCHECKBOX</b> No
_____	_____	\$ _____	<b>FORMCHECKBOX</b> Yes
			<b>FORMCHECKBOX</b> No
_____	_____	\$ _____	<b>FORMCHECKBOX</b> Yes
			<b>FORMCHECKBOX</b> No
_____	_____	\$ _____	<b>FORMCHECKBOX</b> Yes
			<b>FORMCHECKBOX</b> No

C. Total cash and Cash Equivalents of Borrower and its Subsidiaries and Guarantors (Line A plus the aggregate of Line B) \$ \_\_\_\_\_

D. Percentage maintained with Bank and Bank's Affiliates (Line A divided by Line C - expressed as a percentage) \_\_\_\_\_ %

E. Has Borrower maintained compliance with Section 5.9 of the Agreement (which requires that at least 55% of the Dollar Equivalent value of cash and Cash Equivalents (or 50% for a period of time not to exceed 3 Business Days) to be maintained with Bank and Bank's Affiliates unless the Dollar Equivalent value of all of Borrower's, any of its Subsidiaries' and any Guarantor's cash and Cash Equivalents maintained at all financial institutions is less than one hundred ten percent (110.0%) of all outstanding obligations and liabilities owing by Borrower to Bank, in which case, Borrower, any of its Subsidiaries, and any Guarantor shall be required to maintain all of their operating accounts, securities accounts, depository accounts and excess cash with Bank or Bank's Affiliates)?

FORMCHECKBOX Yes   FORMCHECKBOX No

The following are the exceptions with respect to the statements above: (If no exceptions exist, state "No exceptions to note.")

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**EXHIBIT B**  
**LOAN PAYMENT/ADVANCE REQUEST FORM**  
**DEADLINE FOR SAME DAY PROCESSING IS NOON PACIFIC TIME**

Date:

**LOAN PAYMENT:**

Tenaya Therapeutics, Inc.

From Account #

(Deposit Account #)

To Account #

(Loan Account #)

Principal \$

and/or Interest \$

Authorized Signature:

Phone Number:

Print Name/Title:

**LOAN ADVANCE:**

Complete *Outgoing Wire Request* section below if all or a portion of the funds from this loan advance are for an outgoing wire.

From Account #

(Loan Account #)

To Account #

(Deposit Account #)

Amount of Term Loan Advance \$ \_\_\_\_\_ (complete if requesting from Term Loan Availability Amount)

All Borrower's representations and warranties in the Loan and Security Agreement are true and correct in all material respects on the date of the request for an advance; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true and correct in all material respects as of such date:

Authorized Signature:

Phone Number:

Print Name/Title:

**OUTGOING WIRE REQUEST:**

**Complete only if all or a portion of funds from the loan advance above is to be wired.**

Deadline for same day processing is noon, Pacific Time

Beneficiary Name:

Amount of Wire: \$

Beneficiary Bank:

Account Number:

City and State

Beneficiary Bank Transit (ABA) #:

Beneficiary Bank Code (Swift, Sort, Chip, etc.):

**(For International Wires Only)**

Intermediary Bank:

Transit (ABA) #:

For Further Credit to:

Special Instructions

*By signing below, I (we) acknowledge and agree that my (our) funds transfer request shall be processed in accordance with and subject to the terms and conditions set forth in the agreements(s) covering funds transfer service(s), which agreements(s) were previously received and executed by me (us).*

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Authorized Signature:

Print Name/Title:

Phone Number:

2<sup>nd</sup> Signature (if required):

Print Name/Title:

Phone Number:

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**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: November 6, 2024

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)

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**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 September 30, 2024, 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: November 6, 2024

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