UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2022

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: 001-38663

Gritstone bio, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-4859534**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
5959 Horton Street, Suite 300 Emeryville, California	**94608**
(Address of Principal Executive Offices)	**(Zip Code)**

(510) 871-6100
(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, $0.0001 par value per share	**GRTS**	**The Nasdaq Global Select Market**

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

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

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

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

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

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

As of May 3, 2022, there were 72,812,833 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

Gritstone bio, Inc.
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Gritstone bio, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

(In thousands, except share amounts and par value)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 69,158	$ 93,287
Marketable securities	103,004	108,346
Restricted cash	9,395	11,285
Prepaid expenses and other current assets	10,946	7,672
Total current assets	192,503	220,590
Long-term restricted cash	5,290	6,005
Property and equipment, net	22,283	21,622
Lease right-of-use assets	21,832	22,920
Deposits and other long-term assets	1,564	2,352
Long-term marketable securities	—	4,617
Total assets	$ 243,472	$ 278,106
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,641	$ 4,230
Accrued compensation	4,285	6,925
Accrued liabilities	1,350	411
Accrued research and development expenses	3,601	3,706
Lease liabilities, current portion	6,886	7,483
Deferred revenue, current portion	12,324	17,201
Total current liabilities	34,087	39,956
Lease liabilities, net of current portion	18,689	18,936
Deferred revenue, net of current portion	1,505	3,128
Total liabilities	54,281	62,020
Commitments and contingencies (Notes 6 and 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized at March 31, 2022 and December 31, 2021; 72,779,508 and 69,047,878 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	20	20
Additional paid-in capital	619,862	617,523
Accumulated other comprehensive loss	(391)	(73)
Accumulated deficit	(430,300)	(401,384)
Total stockholders' equity	189,191	216,086
Total liabilities and stockholders' equity	$ 243,472	$ 278,106

See accompanying notes to the unaudited condensed consolidated financial statements.

Gritstone bio, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2022	2021
Revenues:		
Collaboration and license revenues	$ 4,745	$ 39,693
Grant revenues	2,446	—
Total revenues	7,191	39,693
Operating expenses:		
Research and development	28,199	24,856
General and administrative	7,955	6,941
Total operating expenses	36,154	31,797
Income (loss) from operations	(28,963)	7,896
Interest income, net	47	27
Net income (loss)	(28,916)	7,923
Other comprehensive loss:		
Unrealized loss on marketable securities	(318)	(3)
Net and comprehensive income (loss)	$ (29,234)	$ 7,920
Net income (loss) per share, basic	$ (0.34)	$ 0.10
Weighted-average number of shares used in computing net income (loss) per share, basic	86,277,599	75,987,372
Net income (loss) per share, diluted	$ (0.34)	$ 0.10
Weighted-average number of shares used in computing net income (loss) per share, diluted	86,277,599	77,464,356

See accompanying notes to the unaudited condensed consolidated financial statements.

Gritstone bio, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

(In thousands, except share amounts)

Three Months Ended March 31, 2022:

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Gain (Loss)	Deficit	Equity
Balance at December 31, 2021	69,047,878	$ 20	$ 617,523	$ (73)	$ (401,384)	$ 216,086
Unrealized loss on marketable securities	—	—	—	(318)	—	(318)
Issuance of common stock upon restricted stock units vesting	215,350	—	—	—	—	—
Tax payments related to shares withheld for vested restricted stock units	—	—	(890)	—	—	(890)
Issuance of common stock for warrant exercises	3,442,567	—	34	—	—	34
Issuance of common stock upon exercise of stock options	73,713	—	64	—	—	64
Stock-based compensation	—	—	3,131	—		3,131
Net loss	—	—	—	—	(28,916)	(28,916)
Balance at March 31, 2022	72,779,508	$ 20	$ 619,862	$ (391)	$ (430,300)	$ 189,191

Three Months Ended March 31, 2021:

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Gain (Loss)	Deficit	Equity
Balance at December 31, 2020	47,552,693	$ 18	$ 493,023	$ —	$ (326,302)	$ 166,739
Offering costs related to the sale of common stock and pre-funded warrants	—	—	(451)	—	—	(451)
Issuance of common stock under Sales Purchase Agreement, net of issuance costs of $330	1,169,591	—	20,839	—	—	20,839
Unrealized loss on marketable securities	—	—	—	(3)	—	(3)
Issuance of common stock under employee stock purchase plan ("ESPP")	109,564	—	279	—	—	279
Issuance of common stock upon exercise of stock options	365,980	—	1,824	—	—	1,824
Stock-based compensation	—	—	2,201	—	—	2,201
Net income	—	—	—	—	7,923	7,923
Balance at March 31, 2021	49,197,828	$ 18	$ 517,715	$ (3)	$ (318,379)	$ 199,351

See accompanying notes to the unaudited condensed consolidated financial statements.

Gritstone bio, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

(In thousands)

	Three Months Ended March 31,	
	2022	2021
Operating activities		
Net income (loss)	$ (28,916)	$ 7,923
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,589	1,595
Net amortization of premiums and discounts on marketable securities	196	107
Stock-based compensation	3,131	2,201
Non-cash operating lease expense	2,332	1,900
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,273)	(182)
Deposits and other long-term assets	787	(7)
Accounts payable	1,861	1,637
Accrued compensation	(2,640)	(2,510)
Accrued and other non-current liabilities	121	(51)
Accrued research and development expenses	(105)	505
Lease liability	(2,034)	(1,950)
Deferred revenue	(6,500)	(514)
Net cash provided by (used in) operating activities	(33,451)	10,654
Investing activities		
Purchase of marketable securities	(28,342)	(89,610)
Maturities of marketable securities	26,573	1,000
Sales of marketable securities	11,215	—
Purchase of property and equipment	(1,812)	(990)
Net cash provided by (used in) investing activities	7,634	(89,600)
Financing activities		
Proceeds from issuance of common stock from public offering	—	21,170
Proceeds from issuance of common stock upon exercise of stock options, warrants, and other	98	1,824
Proceeds from issuance of common stock under the ESPP	—	279
Payments of financing costs	(69)	(5,878)
Payments of financing lease	(56)	—
Tax payments related to shares withheld for vested restricted stock units	(890)	—
Net cash provided by (used in) financing activities	(917)	17,395
Net decrease in cash, cash equivalents and restricted cash	(26,734)	(61,551)
Cash, cash equivalents and restricted cash at beginning of period	110,577	171,048
Cash, cash equivalents and restricted cash at end of period	$ 83,843	$ 109,497
Supplemental disclosures of non-cash investing and financing information		
Property and equipment purchases accrued but not yet paid	$ 1,182	$ 509
Financing costs included in accrued liabilities and accounts payable	$ —	$ 46
Remeasurement of operating lease right-of-use asset for lease modification	$ 228	$ —

See accompanying notes to the unaudited condensed consolidated financial statements.

1. Organization

Description of Business

Gritstone bio, Inc. ("Gritstone" or the "Company") is a clinical-stage biotechnology company developing next generation vaccines for solid tumors and viral diseases. The Company was incorporated in the state of Delaware in August 2015, and is headquartered in Emeryville, California with a site in Cambridge, Massachusetts and a manufacturing facility in Pleasanton, California. The Company operates in one segment.

Liquidity

The Company has incurred operating losses and has an accumulated deficit as a result of ongoing efforts to develop drug product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. The Company had a net loss of $28.9 million for the three months ended March 31, 2022 and net income of $7.9 million for the three months ended March 31, 2021. During the three months ended March 31, 2022, cash used by operating activities was $33.5 million. During the three months ended March 31, 2021, cash provided by operating activities was $10.7 million. The Company had an accumulated deficit of $430.3 million and $401.4 million as of March 31, 2022 and December 31, 2021, respectively. To date, none of the Company's product candidates have been approved for sale and therefore the Company has not generated any revenue from sales of commercial products. Management expects operating losses to continue for the foreseeable future. The Company has funded its operations to date primarily through private placements of its convertible preferred stock, the sale of common stock in public offerings and under an "at the market offering", the private placement of common stock and pre-funded warrants, and through proceeds received from its collaboration arrangements. As of March 31, 2022, the Company had cash, cash equivalents and marketable securities of $172.2 million, which the Company believes will be sufficient to fund its planned operations for a period of at least twelve months following the filing date of this report.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim condensed consolidated financial statements are unaudited and are comprised of the consolidation of the Company and its wholly-owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation. The Company has no unconsolidated subsidiaries or investments accounted for under the equity method.

The accompanying interim condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim reporting.

The interim condensed consolidated financial statements are unaudited and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary for the fair presentation for interim reporting. The results of operations for any interim period are not necessarily indicative of results of operations for any future period.

Certain information and footnote disclosures typically included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. Accordingly, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements as of and for the year ended December 31, 2021, which are included in the Company's Annual Report on Form 10-K, as filed with the SEC on March 10, 2022.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Fair Value of Financial Instruments

U.S. GAAP establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

Fair value is established as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, an established three-tier fair value hierarchy distinguishes between the following:

- Level 1 inputs are quoted prices in active markets that are accessible at the market date for identical assets or liabilities.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3 inputs are unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the assets or liability. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value instrument.

The carrying amounts reflected on the condensed consolidated balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable, accrued compensation and accrued liabilities approximate their fair values due to their short-term nature.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents and marketable securities. Cash, cash equivalents and marketable securities are invested through banks and other financial institutions in the United States. Such deposits may be in excess of federally insured limits. The Company maintains cash equivalents and marketable securities with various high-credit-quality and capitalized financial institutions. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds.

The Company's investment policy limits investments to certain types of securities issued by the U.S. government, its agencies, and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and marketable securities and issuers of marketable securities to the extent recorded on the condensed consolidated balance sheets. As of March 31, 2022, the Company has no off-balance sheet concentrations of credit risk.

Other Risks and Uncertainties

The Company is subject to a number of risks similar to those of other clinical-stage biotechnology companies, including dependence on key individuals; the need to develop commercially viable therapeutics; competition from other companies, many of which are larger and better capitalized; and the need to obtain adequate additional financing to fund the development of its products. The Company currently depends on third-party suppliers for key materials and services used in its research and development manufacturing process and is subject to certain risks related to the loss of these third-party suppliers or their inability to supply the Company with adequate materials and services.

In March 2020, the World Health Organization declared the global novel coronavirus disease ("COVID-19") outbreak a pandemic. To date, the Company's business has not been materially impacted by the COVID-19 pandemic. However, the Company has experienced slowing of patient recruitment and sample collection in its ongoing clinical trials and cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on its financial condition and operations, including ongoing and planned clinical trials. The impact of the COVID-19 pandemic on the financial performance of the Company will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions. These developments and the impact of COVID-19 on the financial markets and the overall economy are highly uncertain. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results may be adversely affected.

Cash, Cash Equivalents and Restricted Cash

Cash equivalents, which consist primarily of highly liquid investments with original maturities of three (3) months or less when purchased, are stated at fair value. These assets include investments in money market funds that invest in U.S. Treasury obligations and certificates of deposit, which are stated at fair value.

The Company has issued letters of credit under certain lease agreements that have been collateralized by cash deposits for an equal amount and are recorded within short-term restricted cash and deposits and other long-term assets on the condensed consolidated balance sheets based on the term of the underlying lease. Additionally, the Company's restricted cash includes payments received under the Coalition for Epidemic Preparedness Innovations ("CEPI") Funding Agreement, dated as of August 14, 2021 (the "CEPI Funding Agreement") and the Gates Foundation Grant Agreement (see Note 8). The Company will utilize the CEPI and Gates Foundation funds as it incurs expenses for services performed under the agreements.

The following table provides a reconciliation of cash, cash equivalents and short-term and long-term restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same amounts shown in the condensed consolidated statements of cash flows (in thousands):

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 69,158	$ 93,287
Restricted cash	9,395	11,285
Long-term restricted cash	5,290	6,005
Total cash, cash equivalents and restricted cash	$ 83,843	$ 110,577

Leases

The Company determines whether the arrangement is or contains a lease at the inception of the arrangement and if such a lease is classified as a financing lease or operating lease. The majority of the Company's leases are classified as operating leases. Leases with a term greater than one year are included in operating lease ROU Assets, lease liabilities, current portion, and lease liabilities, net of current portion in the Company's condensed consolidated balance sheets as of March 31, 2022 and December 31, 2021. The Company has elected not to recognize on the condensed consolidated balance sheets leases with terms of one year or less. Lease liabilities and their corresponding ROU Assets are recorded based on the present value of lease payments over the expected lease term. In determining the net present value of lease payments, the interest rate implicit in lease contracts is typically not readily determinable. As such, the Company estimates the appropriate incremental borrowing rate, which is the rate that would be incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the ROU Assets may be required for items such as initial direct costs paid or incentives received and impairment charges if we determine the ROU Asset is impaired.

The Company considers a lease term to be the non-cancelable period that it has the right to use the underlying asset, including any periods where it is reasonably assured the Company will exercise the option to extend the contract. Periods covered by an option to extend are included in the lease term if the lessor controls the exercise of that option.

The Company recognizes lease expense on a straight-line basis over the expected lease term.

The Company has elected not to separate lease and non-lease components for its leased assets and accounts for all lease and non-lease components of its agreements as a single lease component. The lease components resulting in a ROU Asset have been recorded on the condensed consolidated balance sheets and amortized as lease expense on a straight-line basis over the lease term.

Revenue Recognition

The Company performs research and development under collaboration, license, grant, and clinical development agreements. The Company's revenue primarily consists of collaboration agreements and grant agreements. At contract inception, the Company analyzes a revenue arrangement to determine the appropriate accounting under U.S. GAAP. Currently, the Company's revenue arrangements represent customer contracts within the scope of ASC Topic 606, Revenue from Contracts with Customers (Topic 606) ("ASC 606") or are subject to the contribution guidance in ASC Topic 958-605, Not-for-Profit Entities – Revenue Recognition ("ASC 958-605"), which applies to business entities that receive contributions within the scope of ASC 958-605.

For collaboration agreements, the Company analyzes to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements that are considered to be in the scope of the collaboration guidance and that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of the collaboration guidance and those that are more reflective of a vendor-customer relationship and, therefore, within the scope of the revenue with contracts with customers guidance. Elements of collaboration arrangements that are reflective of a vendor-customer relationship are accounted for pursuant to the revenue from contracts with customers guidance. The terms of the licensing and collaboration agreements entered into typically include payment of one or more of the following: non-refundable, up-front fees; development, regulatory, and commercial milestone payments; payments for manufacturing supply services; and royalties on net sales of licensed products. Each of these payments results in license, collaboration and other revenues, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues. The core principle of the accounting for revenue from contracts with customers guidance is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received in exchange for those goods or services.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company's condensed consolidated balance sheets. If the related performance obligation is expected to be satisfied within the next twelve (12) months, this will be classified in current liabilities. Amounts recognized as revenue prior to receipt are recorded as contract assets in the Company's condensed consolidated balance sheets. If the Company expects to have an unconditional right to receive consideration in the next twelve (12) months, this will be classified in current assets. A net contract asset or liability is presented for each contract with a customer.

At contract inception, the Company assesses the goods or services promised in a contract with a customer and identifies those distinct goods and services that represent a performance obligation. A promised good or service may not be identified as a performance obligation if it is immaterial in the context of the contract with the customer, if it is not separately identifiable from other promises in the contract (either because it is not capable of being separated or

because it is not separable in the context of the contract), or if the performance obligation does not provide the customer with a material right.

The Company considers the terms of the contract and its customary business practices to determine the transaction price. The transaction price is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Variable consideration will only be included in the transaction price when it is not considered constrained, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

If it is determined that multiple performance obligations exist, the transaction price is allocated at the inception of the agreement to all identified performance obligations, based on the relative standalone selling prices. The relative selling price for each performance obligation is estimated using objective evidence if it is available. If objective evidence is not available, the Company uses its best estimate of the selling price for the performance obligation.

Revenue is recognized when, or as, the Company satisfies a performance obligation by transferring a promised good or service to a customer. An asset is transferred when, or as, the customer obtains control of that asset, which for a service is considered to be as the services are received and used. The Company recognizes revenue over time by measuring the progress toward complete satisfaction of the relevant performance obligation, using an appropriate input or output method based on the nature of the good or service promised to the customer.

After contract inception, the transaction price is reassessed at every period end and updated for changes, such as resolution of uncertain events. Any change in the transaction price is allocated to the performance obligations on the same basis as at contract inception.

Management may be required to exercise considerable judgment in estimating revenue to be recognized. Judgment is required in identifying performance obligations, estimating the transaction price, estimating the stand-alone selling prices of identified performance obligations (which may include forecasted revenue, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success) and estimating the progress towards satisfaction of performance obligations.

For grant funding agreements, grant revenue is recognized during the period that the research and development services occur, as qualifying expenses are incurred. The Company concluded that payments received under these grants represent nonreciprocal contributions, as described in ASC 958, Not-for-Profit Entities, and that the grants are not within the scope of ASC 606 as the organization providing the grant does not meet the definition of a customer. Grant revenue relates primarily to the CEPI and Gates Funding Agreements (see Note 8).

Income Taxes

On March 18, 2020, the Families First Coronavirus Response Act (the “FFCR Act”), and on March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) were each enacted in response to the COVID-19 pandemic. The FFCR Act and the CARES Act contain numerous income tax provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property.

On June 29, 2020, Assembly Bill 85 (“A.B. 85”) was signed into California law. A.B. 85 provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than $5.0 million of tax per year. A.B. 85 suspends the use of net operating losses for taxable years 2020 and 2021 for certain taxpayers with taxable income of $1.0 million or more. The carryover period for any net operating losses that are suspended under this provision will be extended. A.B. 85 also requires that business incentive tax credits, including carryovers, may not reduce the applicable tax by more than $5.0 million for taxable years 2020 and 2021.

The FFCR Act, CARES Act and A.B. 85 did not have a material impact on the Company’s condensed consolidated financial statements as of March 31, 2022; however, the Company continues to examine the impacts the FFCR Act, CARES Act and A.B. 85 may have on its business, results of operations, financial condition, liquidity and related disclosures.

Recently Adopted Accounting Pronouncements

In October 2020, the FASB issued ASU No. 2020-10, *Codification Improvements* ("ASU 2020-10"). The standard contains improvements to the FASB Accounting Standards Codification (the "Codification") by ensuring that all guidance that requires or provides an option for an entity to provide information in the notes to financial statements is codified in the disclosure section of the Codification. The standard also improves various topics in the Codification so that entities can apply guidance more consistently on codifications that are varied in nature where the original guidance may have been unclear. The amendments in ASU 2020-10 are effective for the Company for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted. We adopted ASU 2020-10 on January 1, 2022 and the adoption did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

In August 2020, the FASB issued ASU No. 2020-06, *Debt - Debt with Conversion and Other Options* (Subtopic 470-20) and *Derivatives and Hedging - Contracts in Entity's Own Equity* ("ASU 2020-06"). The standard eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, the standard modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The amendments in ASU 2020-06 are effective for the Company as defined by the SEC for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but not earlier than fiscal years beginning after December 15, 2020. The Company does not expect the adoption of ASU 2020-06 to have a material impact on its condensed consolidated financial statements and related disclosures.

3. Cash Equivalents and Marketable Securities

The amortized costs, unrealized gains and losses and fair values of cash equivalents and marketable securities were as follows (in thousands):

	March 31, 2022			
Description	**Amortized Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Cash equivalents:				
Money market funds	$ 45,083	$ —	$ —	$ 45,083
Commercial paper	2,999	—	—	2,999
U.S. treasuries	5,000	—	—	5,000
Asset backed securities	1,001			1,001
Total cash equivalents	54,083	—	—	54,083
Short-term marketable securities:				
Certificates of deposit	4,650	—	(33)	4,617
Commercial paper	35,451	—	(136)	35,315
Corporate debt securities	21,212	—	(94)	21,118
U.S. treasuries	34,792	—	(100)	34,692
U.S. government debt securities	2,000	—	(4)	1,996
Asset backed securities	5,290	—	(24)	5,266
Total short-term marketable securities	103,395	—	(391)	103,004
Total	$ 157,478	$ —	$ (391)	$ 157,087

Description	December 31, 2021			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:				
Money market funds	$ 79,281	$ —	$ —	$ 79,281
Commercial paper	1,000	—	—	1,000
Corporate debt securities	1,031	—	—	1,031
Total cash equivalents	81,312	—	—	81,312
Short-term marketable securities:				
Certificates of deposit	5,600	—	(6)	5,594
Commercial paper	44,990	—	(16)	44,974
Corporate debt securities	26,976	—	(23)	26,953
U.S. treasuries	12,277	—	(8)	12,269
U.S. government debt securities	2,000	—	(1)	1,999
Asset backed securities	16,565	—	(8)	16,557
Total short-term marketable securities	108,408	—	(62)	108,346
Long-term marketable securities:				
Corporate debt securities	1,637	—	(6)	1,631
U.S. treasuries	2,991	—	(5)	2,986
Total long-term marketable securities	4,628	—	(11)	4,617
Total	$ 194,348	$ —	$ (73)	$ 194,275

All marketable securities held as of March 31, 2022 had contractual maturities of less than one year. There have been no material realized gains or losses on marketable securities for the periods presented. As of March 31, 2022, the Company did not hold any individual securities in an unrealized loss position for 12 months or greater. The Company has the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery. No significant facts or circumstances have arisen to indicate that there has been any significant deterioration in the creditworthiness of the issuers of the securities held by us. The Company considered the current and expected future economic and market conditions and determined that the estimate of credit losses was not significantly impacted. Thus, no credit loss existed as of or for the three months ended March 31, 2022 or December 31, 2021. The Company will continue to assess the current and expected future economic and market conditions as further development arises.

See Note 4 for further information regarding the fair value of the Company’s financial instruments.

4. Fair Value Measurements

The Company's financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows (in thousands):

	March 31, 2022			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Cash equivalents:				
Money market funds	$ 45,083	$ 45,083	$ —	$ —
Commercial paper	2,999	—	2,999	—
U.S. treasuries	5,000	5,000	—	—
Asset backed securities	1,001	—	1,001	—
Total cash equivalents	54,083	50,083	4,000	—
Short-term marketable securities:				
Certificates of deposit	4,617	—	4,617	—
Commercial paper	35,315	—	35,315	—
Corporate debt securities	21,118	—	21,118	—
U.S. treasuries	34,692	34,692	—	—
U.S. government debt securities	1,996	—	1,996	—
Asset backed securities	5,266	—	5,266	—
Total short-term marketable securities	103,004	34,692	68,312	—
Total	$ 157,087	$ 84,775	$ 72,312	$ —

	December 31, 2021			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Cash equivalents:				
Money market funds	$ 79,281	$ 79,281	$ —	$ —
Commercial paper	1,000	—	1,000	—
Corporate debt securities	1,031	—	1,031	—
Total cash equivalents	81,312	79,281	2,031	—
Short-term marketable securities:				
Certificates of deposit	5,594	—	5,594	—
Commercial paper	44,974	—	44,974	—
Corporate debt securities	26,953	—	26,953	—
U.S. treasuries	12,269	12,269	—	—
U.S. government debt securities	1,999	—	1,999	—
Asset backed securities	16,557	—	16,557	—
Total short-term marketable securities	108,346	12,269	96,077	—
Long-term marketable securities:				
Corporate debt securities	1,631	—	1,631	—
U.S. treasuries	2,986	2,986	—	—
Total long-term marketable securities	4,617	2,986	1,631	—
Total	$ 194,275	$ 94,536	$ 99,739	$ —

The Company measures the fair value of money market funds based on quoted prices in active markets for identical securities. Commercial paper, corporate debt securities, certificates of deposits, asset backed securities, and U.S. government debt securities are valued taking into consideration valuations obtained from third-party pricing services. These pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of, and broker/dealer quotes on, the same or similar securities, issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

There were no transfers between Level 1 and Level 2 during the periods presented. See Note 3 for further information regarding the amortized cost of our financial instruments.

5. Property and Equipment, Net

Property and equipment and related accumulated depreciation and amortization are as follows (in thousands):

	March 31, 2022	December 31, 2021
Computer equipment and software	$ 997	$ 987
Furniture and fixtures	2,113	2,113
Laboratory equipment	25,057	24,679
Leasehold improvements	14,128	14,128
	42,295	41,907
Less accumulated depreciation and amortization	(23,837)	(22,276)
Construction-in-progress	3,825	1,991
Total property and equipment, net	$ 22,283	$ 21,622

Depreciation and amortization expense was $1.6 million and $1.6 million for the three months ended March 31, 2022 and 2021, respectively.

6. Commitments and Contingencies

Leases

The Company leases office, laboratory and storage space in facilities at several locations:

Emeryville Lease

The Company's principal executive offices in Emeryville, California, consisting of office and laboratory space, are leased pursuant to a 120-month operating lease (the "Emeryville Lease"), which the Company entered into in January 2019, with the obligation to pay rent commencing in November 2019. In conjunction with signing the Emeryville Lease, the Company paid a cash security deposit of $0.6 million, which is recorded as a deposit on the Company's condensed consolidated balance sheet as of March 31, 2022. The Emeryville Lease includes a free rent period, an escalation clause for increased rent and a renewal provision allowing the Company to extend this lease for an additional two five-year periods at the then market rental rate. The lessor provided the Company a tenant improvement allowance for a total of $4.0 million to complete the laboratory and office renovation. The Company has determined the tenant improvements to be lessee owned and therefore has recorded a $8.6 million ROU Asset and a $13.6 million lease liability on the condensed consolidated balance sheet as of March 31, 2022. The Company recorded a $8.7 million ROU Asset and a $13.9 million lease liability on the condensed consolidated balance sheet as of December 31, 2021.

Pleasanton Leases

The Company leases 42,620 square feet of office, cleanroom, and laboratory support manufacturing space in Pleasanton, California pursuant to a non-cancelable operating lease (the "Pleasanton Lease"), which the Company entered into in March 2017, with the obligation to pay rent commencing in December 2017. The Pleasanton Lease includes a free rent period, escalating rent payments and a term that expires on November 30, 2024. The Company may extend the lease term for a period of five years at the then market rental rate. The Company obtained an irrevocable letter of credit in March 2017 in the initial amount of approximately $1.0 million as a security deposit to the Pleasanton Lease, which may be drawn down by the landlord in the event the Company fails to fully and faithfully perform its obligations under the Pleasanton lease. The letter of credit may be reduced based on certain levels of cash and cash equivalents the Company holds. As of March 31, 2022, none of the irrevocable letter of credit amount had been drawn. The Pleasanton Lease further provides that the Company is obligated to pay to the landlord its proportionate share of certain basic operating costs, including taxes and operating expenses.

In connection with the Pleasanton Lease, the Company received a tenant improvement allowance of $1.2 million from the landlord for the costs associated with the design, development and construction of tenant improvements. The unamortized tenant improvement balance is recognized as a component of operating lease ROU Assets on the condensed consolidated balance sheets as of March 31, 2022 and December 31, 2021.

In addition, in May 2019, the Company entered into a 64-month non-cancelable operating lease for additional office space in Pleasanton, California, with an obligation to pay rent commencing in August 2019. In January 2022, the Company amended the lease to add additional leased space and extend the lease expiration date to February 2027.

Cambridge Leases

The Company leases laboratory, office and storage space in several facilities in Cambridge, Massachusetts, pursuant to three separate agreements:

The Company's facility located at 40 Erie Street in Cambridge, Massachusetts is leased pursuant to a 67-month non-cancelable operating lease (the "40 Erie Lease"), which the Company entered into in February 2016, with an obligation to pay rent commencing in October 2016. The lessor provided the Company a tenant improvement allowance for a total of $2.1 million to complete the laboratory and office renovation. In September 2021, the Company executed an amendment to the 40 Erie Lease, which extends its term through April 2025 and provides for monthly base rent amounts, subject to annual increases over the term of the lease.

The Company's facility located at 21 Erie Street in Cambridge, Massachusetts is leased pursuant to a 24-month non-cancelable operating lease (the "21 Erie Lease"), which the Company entered into in September 2018. The 21 Erie Lease has since been amended three times, as a result of which the lease term extends through January 2023.

In March 2021, the Company entered into a 17-month operating lease (the "Cambridge Storage Lease") for additional office and laboratory storage space in Cambridge, Massachusetts, which commenced on April 1, 2021. The Company also paid an insignificant cash security deposit.

In conjunction with the 40 Erie Lease, the 21 Erie Lease and the Cambridge Storage Lease, each as amended (if applicable), the Company has paid certain cash security deposits, which in each case included amounts for the applicable last month's rent and has been classified as part of the operating lease ROU Assets. Of the $0.7 million security deposits, $0.4 million was recorded in prepaids and other assets on the Company's condensed consolidated balance sheet and the remaining $0.3 million was recorded in deposits and other long-term assets on the Company's condensed consolidated balance sheet as of March 31, 2022. Security deposits of $0.7 million are recorded in deposits and other long-term assets on the Company's condensed consolidated balance sheet as of December 31, 2021.

Boston Lease

The Company plans to occupy a newly-built facility in Boston, Massachusetts, with office and laboratory space, in 2023 pursuant to a 120-month operating lease (the "Boston Lease"), which the Company entered into in September 2021. The Boston Lease includes a free rent period, an escalation clause for increased rent and a renewal provision allowing the Company to extend the Boston Lease for two additional five-year periods at the then market rental rate. The landlord provided the Company with a tenant improvement allowance of up to approximately $19.1 million for costs relating to the design, permitting and construction of improvements. The Company's obligation to pay rent is expected to commence in the second half of 2023, subject to free rent periods of three and six months with respect to certain premises. The Company expects to be provided early access to the premises to install fixtures and equipment 60 days prior to the anticipated rent commencement date. The Boston Lease is expected to expire in 2033. The Boston Lease further provides that the Company is obligated to pay to the landlord its proportionate share of certain basic operating costs, including taxes and operating expenses. In connection with the Boston Lease and as a security deposit thereunder, the Company has provided the landlord an irrevocable letter of credit in the amount of approximately $4.6 million, which is collateralized by a restricted cash deposit of $4.7 million, and which may be reduced in the fifth and seventh years of the Boston Lease. As of March 31, 2022, none of the irrevocable letter of credit amount had been drawn.

As of March 31, 2022, the Company has not recognized a ROU Asset or lease liability for the Boston Lease as it did not control the underlying assets at any time in the three months ended March 31, 2022. Under the Boston Lease, the Company is obligated to make minimum lease payments of approximately $79.1 million for the years from 2023 to 2033, which includes rent abatement during the free rent periods.

The Company's operating leases include various covenants, indemnities, defaults, termination rights, security deposits and other provisions customary for lease transactions of this nature.

The components of lease costs, which were included in our condensed consolidated statements of operations and comprehensive income (loss), were as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Lease cost		
Operating lease cost	$ 2,253	$ 1,900
Total lease cost	$ 2,253	$ 1,900

Supplemental information related to leases was as follows:

	Three Months Ended March 31,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities (in thousands):		
Operating cash flows from operating leases	$ 2,034	$ 1,950
New right-of-use assets obtained in exchange for lease obligations (in thousands):		
Operating leases	$ 781	$ —
Weighted-average remaining lease term (years):		
Operating leases	5.3	6.1
Weighted-average discount rate:		
Operating leases	7.4%	9.0%

As of March 31, 2022, minimum annual rental payments under the Company's lease agreements are as follows (in thousands):

	Lease Financing Obligation
Year ending December 31,	
2022 (remaining nine months)	$ 7,621
2023	6,837
2024	12,527
2025	10,658
2026	10,376
Thereafter	62,814
Total minimum payments	110,833
Less: Amounts representing interest expense	(6,144)
Less: Amounts representing lease payments under the Boston Lease	(79,114)
Present value of future minimum lease payments	25,575
Less: Current portion of lease liability	(6,886)
Noncurrent portion of lease liability	$ 18,689

Agreements with CROs

In September 2017, the Company entered into a contract research and development agreement with a third-party contract research organization ("CRO") to provide research, analysis and antibody samples to further the Company's development of its antibody drug candidates. The Company is also obligated to pay the CRO certain milestone payments of up to an aggregate of $36.4 million on achievement of specified events. None of these events had occurred as of March 31, 2022. During the three months ended March 31, 2022, the Company had no research and development expense under the agreement. During the three months ended March 31, 2021, the Company had immaterial research and development expense under the agreement.

In May 2019, the Company entered into a contract research and testing agreement with another third-party CRO to provide antibody discovery related services. In March 2022, the Company notified that CRO of its intent to terminate the agreement effective in May 2022. Until the effective date of the termination, the Company is obligated to pay the CRO certain milestone payments of up to $34.8 million on achievement of specified events. None of these

events had occurred as of March 31, 2022. No research and development expense was recorded under the agreement during the three months ended March 31, 2022 and 2021.

Guarantees and Indemnifications

The Company, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws, and pursuant to indemnification agreements with certain of its officers and directors, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, with respect to which the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period lasts as long as an officer or director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance limits the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations for any period presented.

7. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	March 31, 2022	December 31, 2021
Prepaid research and development-related expenses	$ 5,728	$ 2,672
Net contract asset	—	1,385
Collaboration receivable	2,235	688
Prepaid insurance	1,314	1,769
Interest and other receivables	224	292
Facilities-related deposits	455	—
Other	990	866
Total prepaid expenses and other current assets	$ 10,946	$ 7,672

Deposits and Other Long-Term Assets

Deposits and other long-term assets consist of the following (in thousands):

	March 31, 2022	December 31, 2021
Lease security deposits	$ 934	$ 1,305
Prepaid research and development-related expenses	630	1,047
Total deposits and other long-term assets	$ 1,564	$ 2,352

8. Collaboration and License Agreements and Grant Revenue

2seventy bio, Inc.

In August 2018, the Company entered into a Research Collaboration and License Agreement with bluebird bio, Inc. ("bluebird"). In November 2021, bluebird assigned the Research Collaboration and License Agreement (the "2seventy Agreement"), to its affiliate, 2seventy bio, Inc. ("2seventy"), in connection with bluebird's restructuring and subsequent spin-out of 2seventy. Under the terms of the 2seventy Agreement, the Company provides to 2seventy tumor-specific targets across several tumor types and, in certain cases, T cell receptors (TCR) directed to those targets. The Company received a non-refundable upfront payment of $20.0 million, and 2seventy also concurrently acquired 768,115 shares of the Company's Series C convertible preferred stock for $10.0 million at $13.04 per share. Per the 2seventy Agreement, 2seventy was also provided an option to acquire shares of the Company's common stock at the same price as all other investors in connection with the Company's initial public offering ("IPO"). In October 2018,

2seventy purchased 666,667 shares of the Company's common stock at the price to the public of $15.00 per share for a total of $10.0 million. Under the terms of the 2seventy Agreement, the Company is eligible to earn development, regulatory, and sales-based milestones in an amount of up to $1.2 billion, and single-digit royalties on sales of products that utilize the technology subject to the 2seventy Agreement. None of these events had occurred as of December 31, 2021, and no royalties were due from the sale of licensed products.

In August 2019, the Company entered into a First Amendment to the 2seventy Agreement, which extended the timeline for the Company and 2seventy to execute a Patient Selection Services Agreement from within one year to within two years after the Effective Date of the 2seventy Agreement. In August 2020, the Company entered into a Second Amendment, which extended the timeline of the Patient Selection Services Agreement to within three years and also extended the Tissue Analysis Period from February 28, 2021 to June 30, 2021. In April 2021, the Company entered into a Third Amendment, which removed the Patient Selection Services Agreement in its entirety and extended the Tissue Analysis Period from June 30, 2021 to December 31, 2021. The amendments were entered into for administrative purposes, and the Company determined the amendments were not a modification of contract under the contract with customers guidance.

2seventy may terminate the 2seventy Agreement by giving a 120-day prior written notice to the Company at any time after the effective date of the agreement. Unless terminated early, the agreement has a term that ends upon the last payment owed by the Company on a licensed product. The 2seventy Agreement may be terminated for cause by either party based on uncured material breach by the other party or bankruptcy of the other party. Upon early termination, all ongoing activities under the agreement and all mutual collaboration, development and commercialization licenses and sublicenses will terminate. The licenses granted by the Company to 2seventy under the licensed intellectual property will remain in effect in accordance with their respective terms. Additionally, all of 2seventy's payment obligations that have not yet accrued related to future milestone and royalty payments will be reduced by 50% for the remainder of the agreement term.

The Company concluded that 2seventy is a customer, and the contract is not subject to guidance on collaborative arrangements. This is because the Company granted to 2seventy a license to its intellectual property and provided research and development services, all of which are outputs of the Company's ongoing activities, in exchange for consideration.

The Company identified the following three material promises under the 2seventy Agreement: (i) transfer of a license to intellectual property and related technology know-how ("License and Know-How"); (ii) the obligation to perform target selection and TCR generation services ("Research and Development Services"); and (iii) participation on the Joint Steering Committee (the "JSC"). The Company provided to 2seventy standard indemnification and protection of licensed intellectual property, which is part of assurance that the license meets the contract's specifications and is not an obligation to provide goods or services.

The Company considered that the License and Know-How has standalone functionality, was considered to be functional intellectual property, and is capable of being distinct. However, the Company determined that the License and Know-How is not distinct from the Research and Development Services or participation on the JSC within the context of the 2seventy Agreement, because 2seventy is dependent on the Company to execute the Research and Development Services and participate on the JSC in order for 2seventy to benefit from the License and Know-How. As such, the License and Know-How is combined with the Research and Development Services and participation on the JSC into a single performance obligation, and the transaction price under this arrangement will be allocated to this single performance obligation.

The Company has also determined that all other goods or services that are contingent upon 2seventy reaching various milestones are not considered performance obligations at the inception of the arrangement.

The transaction price at the inception of the 2seventy Agreement consisted of the upfront payment of $20.0 million and the $10.0 million received from 2seventy for the purchase of the Company's Series C convertible preferred stock. The sale of the Series C convertible preferred stock was not considered to be a performance obligation, as it was a separate financing component of the transaction. Accordingly, $10.0 million of the transaction price was allocated to the issuance of 768,115 shares of Series C convertible preferred stock at fair value of $13.04 per share and recorded in stockholders' equity.

The variable consideration related to the remaining development, regulatory, and sales-based milestones payments has not been included in the initial transaction price and continues to be fully constrained as of December 31, 2021. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt

of the milestones is outside the control of the Company and contingent upon initiation of clinical trials for early-stage targets and 2seventy's development efforts. Any variable consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur, as they were determined to relate predominantly to the License and Know-How granted to 2seventy. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

For revenue recognition purposes, the Company determined that the duration of the 2seventy Agreement began on the effective date in August 2018 and ends upon completion of the Research and Development Services, which is also when the participation on the JSC is no longer an obligation. The contract duration is defined as the period in which parties to the contract have present enforceable rights and obligations. The Company also analyzed the impact of 2seventy terminating the agreement prior to August 2023 and determined, considering both quantitative and qualitative factors, that there were substantive non-monetary penalties to 2seventy for doing so.

Revenue is recognized when, or as, the Company satisfies its performance obligation by transferring the promised services to 2seventy. Revenue is being recognized over time using a cost-based input method, based on internal labor cost effort to perform the research services, since the internal labor cost incurred over time is thought to best reflect the transfer of services to 2seventy. In applying a cost-based input method of revenue recognition, we use actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. A cost-based input method of revenue recognition requires us to make estimates of costs to complete the performance obligation. The cumulative effect of any revisions to estimated costs to complete the performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

During the three months ended March 31, 2022 and 2021, the Company recognized $4.0 million and $0.7 million, respectively, in collaboration revenue under the 2seventy Agreement. The amount of collaboration revenue recognized during the three months ended March 31, 2022 included a cumulative catch-up adjustment increasing contribution revenue by $3.5 million due to revisions to estimated costs to complete the remaining performance obligation. Deferred revenue of $4.7 million and $8.7 million was recorded on the condensed consolidated balance sheets in both current and long-term liabilities as of March 31, 2022 and December 31, 2021, respectively. Deferred revenue relates to the performance obligations identified under the 2seventy Agreement and will be recognized over the period the performance obligations are expected to be satisfied, which is currently estimated to be through September 2023.

Changes in the deferred revenue balance during the three months ended March 31, 2022 for the 2seventy Agreement are as follows (in thousands):

	Deferred Revenue
Balance at December 31, 2021	$ 8,725
Additions	—
Deductions	(3,994)
Balance at March 31, 2022	$ 4,731

There were no receivables or net contract assets recorded as of March 31, 2022 and December 31, 2021 associated with the 2seventy Agreement.

Gilead Sciences, Inc.

In January 2021, the Company entered into a Collaboration, Option and License Agreement (the "Gilead Collaboration Agreement") with Gilead Sciences, Inc. ("Gilead") to research and develop a vaccine-based immunotherapy as part of Gilead's efforts to find a curative treatment for HIV infection. Under the terms of the Gilead Collaboration Agreement, the Company granted to Gilead an exclusive, worldwide license to develop and commercialize a HIV-specific therapeutic vaccine utilizing the Company's technology. Gilead is responsible for conducting all development and commercialization activities beginning with a Phase 1 study, and the Company is responsible for contributing to preclinical research studies and participation in a joint steering committee (collectively, "research and development activities"). Concurrently with execution of the Gilead Collaboration Agreement, the Company and Gilead entered into a Supply Agreement (the "Gilead Supply Agreement") under which the Company will supply research product and GMP product ("Product Supply") that may be required under the Gilead

Collaboration Agreement until Gilead completes its first GMP product batch, and the Company will participate in a joint manufacturing team (collectively, "product supply activities"). In addition, the Company also concurrently entered into a Stock Purchase Agreement (the "Gilead Stock Purchase Agreement") under which Gilead acquired, in a private placement transaction, 1,169,591 shares of the Company's common stock. The common shares were issued to Gilead with certain registration rights and certain standstill and market stand-off provisions. The Company determined that these concurrent contracts represent a combined arrangement ("the Gilead Arrangement").

Under the Gilead Collaboration Agreement, the Company received a non-refundable upfront payment of $30.0 million. Under the Gilead Collaboration Agreement and the Gilead Supply Agreement, the Company will receive additional reimbursement payments for expenses incurred in the research and development activities and product supply activities. Under the Gilead Stock Purchase Agreement, the common shares were sold at a price of $25.65 per share for a total of $30.0 million. The Company's common stock at fair value on closing was $18.10 per share. If Gilead decides to move forward with development beyond the initial Phase 1 study (the "Option"), the Company will receive a $40.0 million non-refundable option fee and will be eligible to receive up to an aggregate of $685.0 million if certain clinical, regulatory and commercial milestones are achieved, as well as tiered royalties ranging from the mid-single digits to low double-digits on net sales of a therapeutic product utilizing its technology. None of these events had occurred as of March 31, 2022 and no royalties were due from the sale of licensed products.

Gilead may terminate the Gilead Collaboration Agreement for convenience by giving a 90-day prior written notice to the Company at any time after the effective date of the agreement. Unless terminated early, the agreement has a term that ends upon the expiration of the royalty term, or, if the Option is not exercised, by the end of the Option term. The Gilead Collaboration Agreement may be terminated for cause by either party based on uncured material breach by the other party, insolvency of the other party, or patent challenge. Upon early termination, all ongoing activities under the agreement and all mutual collaboration, development and commercialization licenses and sublicenses will terminate. The licenses granted by the Company to Gilead under the licensed intellectual property will remain in effect in accordance with their respective terms. Additionally, if terminated early by Gilead for convenience or by the Company for material breach or insolvency, all of Gilead's payment obligations for reimbursable costs or for future milestone and royalty payments remain. If terminated early by Gilead for material breach or insolvency, all of Gilead's unaccrued payment obligations related to future milestone and royalty payments will be reduced by 50% for the remainder of the agreement term. Furthermore, Gilead may terminate the Gilead Supply Agreement without cause by giving six months prior written notice and any active orders with 60-day notice without terminating the agreement, and either party may terminate based on an uncured material breach, insolvency of the other party, or in the event that the Gilead Collaboration Agreement is terminated. Upon termination, the Company will deliver all supply products that have been produced and destroy, reimburse or deliver materials that Gilead has reimbursed, and Gilead must pay for any manufacturing costs that the Company has actually incurred or committed to pay, including any cancellation costs owed to subcontractors.

The Company concluded that Gilead is a customer and therefore revenue recognition should be accounted for in accordance with ASC 606, because the Company granted to Gilead licenses to its intellectual property and will provide research and development services and Supply of Product, as defined below, all of which are outputs of the Company's ongoing activities, in exchange for consideration. The Option, if exercised by Gilead, will be considered a modification that increases the scope of the arrangement beyond the Option Term.

The Company identified the following performance obligations under the Gilead Collaboration Agreement: (i) licenses including an exclusive (in the HIV field), royalty-free, worldwide collaboration license and transfer of know-how and an exclusive (in the HIV field) worldwide, royalty-bearing development and commercial license subject to restrictions on its use during the Option Term and an exclusive option to release such restrictions; (ii) preclinical research and development activities, manufacturing-related activities, and participation on a Joint Steering Committee; and (iii) product supply, including research and GMP product, until Gilead completes its first GMP batch, and participation on a Joint Manufacturing Team.

The Company considered that the licenses and know-how have standalone functionality, are considered to be functional intellectual property and are capable of being distinct. The Company also determined that the research and development activities and product supply by Gritstone could be provided by resources otherwise available to Gilead and thus are capable of being distinct.

The Company has also determined that the pricing for optional goods and services and release of license restrictions upon exercise of the Option do not constitute material rights and are not a potential performance obligation. The Company evaluated whether there is an interdependence between the promises and determined that the licenses

are a combined solution and the predominant performance obligation, while the other promises are separately identifiable in the context of the contract; however, the research and development activities are dependent on the research product supply, which is accounted for as a combined performance obligation. As a result, the Company identified three performance obligations in the Gilead Arrangement: (i) exclusive licenses and know-how, (ii) research and development activities and product supply, and (iii) GMP product supply.

The transaction price at the inception of the Gilead Collaboration Agreement consisted of the upfront payment of $30.0 million and the $30.0 million received for the sale of the Company's common stock. The sale of the common stock was not considered to be a performance obligation, as it was a separate financing component of the transaction. Accordingly, $21.2 million of the transaction price was allocated to the issuance of 1,169,591 shares of the Company's common stock at fair value on closing of $18.10 per share and recorded in stockholders' equity. The remaining $8.8 million of the common stock purchase price in excess of the fair value of the shares received is added to the transaction price for the Gilead Collaboration Agreement. In addition, the initial transaction price includes estimated variable consideration for budgeted reimbursement of research and development costs and product supply. The variable consideration related to reimbursable costs and product supply has been constrained as of March 31, 2022 based on the current research and development plan forecast. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company determined that the variable consideration for the $40.0 million option exercise fee and for the development, regulatory, and sales-based milestones payments were probable of significant revenue reversal as their achievement was highly dependent on factors outside the Company's control. As a result, these payments were fully constrained and were not included in the transaction price. Any variable consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur, as they were determined to relate predominantly to the exclusive licenses and know-how granted to Gilead.

The transaction price is allocated to the performance obligation based upon relative standalone selling prices, which were determined for the exclusive licenses and know-how using an adjusted market approach and for the research and development activities and product supply using a cost plus reasonable margin approach. Variable consideration is allocated to the specific performance obligations to which it relates.

For revenue recognition purposes, the Company determined that the duration of the contract began on the effective date in January 2021 and ends upon (i) the completion of the Option term, which is expected to end two to four years after the effective date, if the Option is not exercised or (ii) the expiration of the royalty-term on a product-by-product and country-by-country basis. The Company also analyzed the impact of Gilead terminating the agreement prior to the end of the Option term and determined, considering both quantitative and qualitative factors, that there were substantive non-monetary penalties to Gilead for doing so.

Revenue for the exclusive licenses and know-how was recognized on the effective date of the Gilead Collaboration Agreement at the point in time that the licenses are effective. The research and development activities and product combined performance obligation and the GMP product supply performance obligation are recognized over time when, or as, the Company transfers the promised goods and services to Gilead. Research and development service and product supply revenues will be recognized over time using a cost-based input method, based on internal and external labor cost effort to perform the services, costs to acquire research materials, and costs of product supply, since the costs incurred over time are thought to best reflect the transfer of goods and services to Gilead. In applying a cost-based input method of revenue recognition, we use actual costs incurred relative to estimated total costs to fulfill each performance obligation. A cost-based input method of revenue recognition requires us to make estimates of costs to complete the performance obligation. The cumulative effect of any revisions to estimated costs to complete the performance obligation and associated variable consideration will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

For the three months ended March 31, 2022, the Company did not record any license revenue and recorded $0.7 million as collaboration revenue as a result of satisfying its performance obligations by transferring the promised goods and services estimated by the costs incurred for the Gilead Collaboration Agreement. For the three months ended March 30, 2021, the Company recognized $38.6 million as license revenue and $0.3 million as collaboration revenue as a result of satisfying its performance obligations by transferring the promised goods and services estimated by the costs incurred for the Gilead Collaboration Agreement. There was no contract asset recorded on the condensed consolidated balance sheet as of March 31, 2022. A contract asset of $1.4 million was recorded on the condensed

consolidated balance sheet as of December 31, 2021 for supply costs that were incurred during the year ended December 31, 2021, but not billable until future periods when the asset is released. The contract asset relates to the performance obligations yet to be satisfied identified under the Gilead Collaboration Agreement. There was $0.1 million recorded as deferred revenue as of March 31, 2022 and no deferred revenue as of December 31, 2021 associated with the Gilead Collaboration Agreement.

Changes in the contract asset and deferred revenue balance during the three months ended March 31, 2022 for the Gilead Collaboration Agreement are as follows (in thousands):

	Contract Asset	Deferred Revenue
Balance at December 31, 2021	$ 1,385	$ —
Additions	123	99
Deductions	(1,508)	—
Balance at March 31, 2022	$ —	$ 99

There was $2.2 million and $0.7 million of receivables recorded on the condensed consolidated balance sheet as a current asset in the prepaid expenses and other current assets balance as of March 31, 2022 and December 31, 2021, respectively, associated with the Gilead Collaboration Agreement.

The Company deferred $0.1 million in incremental costs to acquire the Gilead Collaboration Agreement in the first quarter of 2021 allocated to performance obligations recognized over time, which will be recognized over time in each period proportionate to revenue recognition. As of March 31, 2022, deferred contract acquisition costs were zero. Deferred contract acquisition costs amortized during the three months ended March 31, 2022 and 2021 were negligible.

Arbutus Biopharma Corporation

In October 2017, the Company entered into an Exclusive License Agreement with Arbutus Biopharma Corporation (“Arbutus”) and its wholly-owned subsidiary, Protiva Biotherapeutics Inc. Certain terms of the agreement were modified by amendment in July 2018 (such amended license agreement, the Arbutus License Agreement). Under the Arbutus License Agreement, Arbutus granted the Company exclusive license rights under certain intellectual property related to Arbutus’ lipid nanoparticle (LNP) technology. During the three months ended March 31, 2022 and 2021, the Company had no research and development expense under the Arbutus License Agreement. The Company is obligated to pay Arbutus certain milestone payments up to $123.5 million on achievement of specified events, and royalties on sales of its licensed products. Following the acceptance of our investigational new drug application for GRANITE by the U.S. Food and Drug Administration (the “FDA”), the Company made a $2.5 million development milestone payment to Arbutus in September 2018 that was recorded as research and development expense. In August 2019, a milestone was met following the initial patient treatment of SLATE in the Company’s GO-005 clinical trial. In 2019, the Company recorded $3.0 million as research and development expense in connection with the milestone. None of the other events had occurred as of March 31, 2022, and no royalties were due from the sale of licensed products.

Non-Profit Hospital Cancer Center

In January 2016, the Company entered into an Exclusive License Agreement with a non-profit hospital cancer center. Under the license agreement, the Company has an exclusive license to utilize certain patents and know-how relating to immunotherapy for an insignificant upfront payment, cash milestone payments on achievement of specified events, and a low single digit royalty on sales of licensed products. The achievement of the milestones and payment of royalties is dependent upon obtaining regulatory approval. Upon achievement of a milestone related to the Company’s Phase 1 clinical trial for GRANITE, GO-004, in December 2018 the Company recorded an insignificant amount to research and development expense for amounts owed to the Hospital Cancer Center, which was paid to the hospital in February 2019. None of the other milestone events had occurred as of March 31, 2022 and no royalties were due from the sales of licensed products.

Genevant Sciences GmbH

In October 2020, the Company entered into an Option and License and Development Agreement (the “2020 Genevant License Agreement”) with Genevant Sciences GmbH (“Genevant”), pursuant to which Genevant granted the Company exclusive license rights under certain intellectual property related to Genevant’s LNP technology for a

single therapeutic indication, and the Company agreed to pay Genevant an initial payment of $2.0 million, up to an aggregate of $71.0 million in specified development, regulatory, and commercial milestones, and low to mid-single digit royalties on net sales of licensed products. The upfront payment of $2.0 million was included in research and development expense for the year ended December 31, 2020. The 2020 Genevant License Agreement expands Gritstone's intellectual property rights to such LNP technology originally obtained pursuant to the Company's license agreement with Arbutus. Genevant is a spin-off of Arbutus. Prior to the 2020 Genevant License Agreement, the Company licensed Arbutus' LNP technology for indications in the oncology space. The remainder of Arbutus' IP portfolio was transferred to Genevant in the spin-off. In March 2022, a milestone in the amount of $1.0 million was met, which was included in research and development expense for the three months ended March 31, 2022.

Pursuant to the 2020 Genevant License Agreement, Genevant also granted the Company certain options to license the LNP technology for additional therapeutic indications of up to $1.5 million for each indication and $1.0 million to extend the option term. The 2020 Genevant License Agreement continues in effect until the last to expire royalty term or early termination. It is terminable by the Company for convenience with 90 days prior written notice or immediately if based on certain product safety or efficacy or regulatory criteria. Either party may terminate the agreement for material breach, subject to a cure period, and Genevant may terminate the agreement if the Company challenges a licensed patent.

In January 2021, the Company entered into a Non-Exclusive License and Development Agreement (the "2021 Genevant License Agreement") with Genevant. Pursuant to the 2021 Genevant License Agreement, the Company obtained a nonexclusive license to Genevant's LNP technology to develop and commercialize self-amplifying RNA ("samRNA") vaccines against SARS-CoV-2, the virus that causes COVID-19. Under the 2021 Genevant License Agreement, the Company made a $1.5 million upfront payment to Genevant, and Genevant is eligible to receive from the Company up to an aggregate of $141.0 million in contingent milestone payments per product, plus certain tiered royalties, upon achievement of development and commercial milestones. In certain scenarios, in lieu of milestones and royalties, Genevant will be entitled to a percentage of amounts that the Company receives from sublicenses under the 2021 Genevant License Agreement, subject to certain conditions. In March 2021, a milestone in the amount of $1.0 million was met following the initial patient treatment in the Phase 1 clinical trial conducted through the NIAID-supported Infectious Diseases Clinical Research Consortium ("IDCRC"). Both the $1.5 million upfront and $1.0 million milestone payments were recorded as research and development expense for the three months ended March 31, 2021. None of the other milestone events had occurred as of March 31, 2022.

Coalition for Epidemic Preparedness Innovations

On August 14, 2021, the Company entered into the CEPI Funding Agreement with CEPI, under which CEPI agreed to provide funding of up to $20.6 million to the Company to advance the Company's program, which is developing a second-generation COVID-19 vaccine, with an initial clinical trial in South Africa. Under the terms of the agreement, CEPI will fund a multi-arm Phase 1 study evaluating the CORAL program's samRNA vaccine in naïve, convalescent, and HIV+ patients. The study will evaluate two different samRNA vaccine constructs that each target both the spike protein and other SARS-CoV-2 targets and are designed to drive both robust B and T cell immune responses. The funding will also support pre-clinical studies, scale-up and formulation development to enable manufacturing of large quantities of stable vaccine product.

Under the terms of the CEPI Funding Agreement, among other things, the Company and CEPI agreed on the importance of global equitable access to the vaccine produced pursuant to the CEPI Funding Agreement. The vaccine, if approved, is expected to be made available to the COVAX Facility for procurement and allocation. The COVAX Facility aims to deliver equitable access to COVID-19 vaccines for all countries, at all levels of development, that wish to participate.

The scope and continuation of the CEPI Funding Agreement may be amended depending on ongoing developments of the COVID-19 outbreak and the success of the Company's COVID-19 vaccine candidate developed under the CEPI Funding Agreement relative to other third-party COVID-19 vaccine candidates or treatments. If the World Health Organization (WHO), CEPI or a regulatory authority having jurisdiction over a clinical trial performed under the CEPI Funding Agreement determines that a third-party product candidate has substantially greater potential than the Company's COVID-19 vaccine candidate developed under the CEPI Funding Agreement and should be prioritized instead for a particular trial, the Company must consider in good faith any written request of CEPI not to proceed with a clinical trial of such COVID-19 vaccine candidate (the determination of whether to proceed or not with such trial shall be made by the Company in its sole discretion). In addition, CEPI has the right to unilaterally terminate

the CEPI Funding Agreement upon prior written notice if CEPI determines that (i) there are material safety, regulatory, scientific misconduct or ethical issues with the project undertaken by the Company under the CEPI Funding Agreement, (ii) the project undertaken by the Company under the CEPI Funding Agreement should be terminated, (iii) the Company becomes unable to discharge its obligations under the CEPI Funding Agreement, (iv) the Company fails to meet certain criteria set forth in the CEPI Funding Agreement, or (v) the Company commits fraud or a financial irregularity, as such terms are defined in the CEPI Funding Agreement.

In December 2021, the Company and CEPI entered into an amendment to the CEPI Funding Agreement, under which CEPI agreed to provide additional funding up to $5.0 million, for a total of up to $25.6 million, to the Company to conduct a Phase I clinical trial of the Company's Omicron vaccine candidate in South Africa.

CEPI advances grant funds upon request by the Company consistent with the agreed upon amounts and schedules as provided in the CEPI Funding Agreement. The first tranche of funding of $11.3 million was received in September 2021.

Payments received in advance that are related to future performance are deferred and recognized as grant revenue when the research and development activities are performed. Cash payments received under the CEPI Funding Agreement are restricted as to their use until expenditures contemplated in the funding agreement are incurred. During the three months ended March 31, 2022, the Company recognized grant revenue of $2.2 million under the CEPI Funding Agreement. In the year ended December 31, 2021, the Company recognized grant revenue of $1.5 million under the CEPI Funding Agreement. As of March 31, 2022 and December 31, 2021, short term deferred revenue of $7.0 million and $9.4 million, respectively, was recorded on the condensed consolidated balance sheet. Deferred revenue will be recognized over the period in which the funding agreement activities related to the first tranche of funding are expected to take place, which is currently estimated to be through the end of the year 2022. As of March 31, 2022 and December 31, 2021, $7.0 million and $9.4 million, respectively, was recorded as short-term restricted cash on the condensed consolidated balance sheet.

Changes in the deferred revenue balance during the three months ended March 31, 2022 for the CEPI Funding Agreement are as follows (in thousands):

	Deferred Revenue
Balance at December 31, 2021	$ 9,379
Additions	—
Deductions	(2,415)
Balance at March 31, 2022	$ 6,964

Gates Foundation

In November 2021, the Company entered into a Grant Agreement with the Gates Foundation ("Gates Grant Agreement"), under which the Company will develop an optimal immunogen in the context of a therapeutic human papillomavirus ("HPV") vaccine. In consideration for the work to be performed, the Gates Foundation provided the Company with an upfront payment of $2.2 million in December 2021, and future funding of $1.0 million is expected to be received by the Company in the first quarter of 2023, for a total grant amount of up to $3.2 million.

Payments received in advance that are related to future performance are deferred and recognized as grant revenue when the research and development activities are performed. Cash payments received under the Gates Grant Agreement are restricted as to their use until expenditures contemplated in the funding agreement are incurred. The Company did not recognize any grant revenue under the Gates Grant Agreement in 2021. During the three months ended March 31, 2022, the Company recognized $0.2 million in revenue under the Gates Grant Agreement. As of March 31, 2022, short-term deferred revenue of $2.0 million was recorded on the condensed consolidated balance sheet. Deferred revenue will be recognized over the period in which the funding agreement activities related to the first tranche of funding are expected to take place, which is currently estimated to be through early 2023.

Changes in the deferred revenue balance during the three months ended March 31, 2022 for the Gates Grant Agreement are as follows (in thousands):

	Deferred Revenue
Balance at December 31, 2021	$ 2,225
Additions	—
Deductions	(190)
Balance at March 31, 2022	$ 2,035

9. Stockholders' Equity

The Company's amended and restated certificate of incorporation provides for 300,000,000 shares of common stock and 10,000,000 shares of preferred stock authorized for issuance, each with a par value of $0.0001 per share.

As of March 31, 2022 and December 31, 2021, no shares of preferred stock were issued and outstanding.

As of March 31, 2022 and December 31, 2021, there were 72,779,508 and 69,047,878 shares of common stock issued and outstanding, respectively. Holders of the Company's common stock are entitled to one vote per share.

Sale of Common Stock and Pre-Funded Warrants

In October 2019, the Company filed a Registration Statement on Form S-3 (the "2019 Shelf Registration Statement") with the SEC, covering the offering of up to $250.0 million of common stock, preferred stock, debt securities, warrants and units. The 2019 Shelf Registration Statement included a prospectus supplement covering the issuance and sale of up to $75.0 million of the Company's common stock, from time to time, through the "at-the-market" offering program (the "2019 ATM Offering Program") under the Securities Act of 1933, as amended (the "Securities Act"). The SEC declared the 2019 Shelf Registration Statement effective on November 8, 2019.

In connection with the 2019 ATM Offering, in October 2019, the Company entered into a sales agreement (the "2019 Sales Agreement") with Cowen and Company, LLC ("Cowen"), pursuant to which Cowen acts as its sales agent and, from time to time, offers and sells shares of the Company's common stock having an aggregate offering price of up to $75.0 million. Cowen is entitled to compensation for its services equal to up to 3.0% of the gross proceeds of any shares of common stock sold under the 2019 Sales Agreement. In addition, the Company agreed to reimburse a portion of Cowen's expenses in connection with the 2019 ATM Offering up to $50,000. During the year ended December 31, 2021, the Company issued and sold 3,990,869 shares of its common stock through its 2019 ATM Offering Program and received net proceeds of approximately $9.8 million, net of commissions and other offering costs. During the three months ended March 31, 2022, there have been no sales of shares of the Company's common stock through its 2019 ATM Offering Program.

In December 2020, the Company entered into two private placement financing transactions (collectively, the "First PIPE Financing"), as follows: (i) to sell 5,543,351 shares of its common stock at a price of $3.34 per share and pre-funded warrants (the "Warrants") to purchase 27,480,719 shares of common stock at a price of $3.34 per share (of which $3.33 per share was prepaid by each purchaser), and (ii) to sell an additional 4,043,127 shares of its common stock at a price per share of $3.71. In connection with the First PIPE Financing, the Company received aggregate net proceeds of approximately $119.8 million. The Warrants are exercisable upon issuance at an exercise price of $0.01 per share.

The outstanding Warrants generally may not be exercised if the holder's aggregate beneficial ownership would be more than 9.99% of the total issued and outstanding shares of the Company's common stock following such exercise. The exercise price and number of shares of common stock issuable upon the exercise of the Warrants (the "Warrant Shares") are subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Warrant agreements. Under certain circumstances, the Warrants may be exercisable on a "cashless" basis. In connection with the issuance and sale of the common stock and Warrants, the Company granted the purchasers certain registration rights with respect to the Warrants and the Warrant Shares.

The Warrants were classified as a component of permanent stockholders' equity within additional paid-in-capital and were recorded at the issuance date using a relative fair value allocation method. The Warrants are equity

classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, such Warrants do not provide any guarantee of value or return. The Company valued the Warrants at issuance, concluding their sales price approximated their fair value, and allocated net proceeds from the sale proportionately to the common stock and Warrants, of which $87.7 million, net of issuance costs, was allocated to the Warrants and recorded as a component of additional paid-in-capital.

In September 2021, the Company completed a PIPE financing transaction, in which it sold 5,000,000 shares of its common stock at a price of $11.00 per share pursuant to a securities purchase agreement entered into on September 16, 2021 (the "Second PIPE Financing"). The Company received aggregate net proceeds of approximately $52.7 million after deducting placement agent commissions and offering expenses payable by the Company. In connection with the issuance and sale of the common stock, the Company filed a registration statement with the SEC registering the resale of the shares of common stock issued in the Second PIPE Financing.

In March 2022, the Company filed a Registration Statement on Form S-3 with the SEC (the "2022 Shelf Registration Statement"), covering the offering of up to $250.0 million of common stock, preferred stock, debt securities, warrants and units. The 2022 Shelf Registration Statement included a prospectus supplement covering the issuance and sale of up to $100.0 million of the Company's common stock, from time to time, through the "at-the-market" offering program (the "2022 ATM Offering Program") under the Securities Act. As of May 3, 2022, the SEC has not yet declared the 2022 Shelf Registration Statement effective.

In connection with the 2022 ATM Offering, in March 2022, the Company also entered into a sales agreement (the "2022 Sales Agreement") with Cowen, pursuant to which Cowen will act as its sales agent and, from time to time, offer and sell shares of the Company's common stock having an aggregate offering price of up to $100.0 million. Cowen is entitled to compensation for its services equal to up to 3.0% of the gross proceeds of any shares of common stock sold under the 2022 Sales Agreement. In addition, the Company agreed to reimburse a portion of Cowen's expenses in connection with the 2022 ATM Offering up to $50,000. As of March 31, 2022, there have been no sales of shares of the Company's common stock under the 2022 ATM Offering Program.

Common Stock Warrants

As of March 31, 2022, the following warrants to purchase shares of the Company's common stock were issued and outstanding:

Issue Date	Expiration Date	Exercise Price	Number of Warrants Outstanding
December 28, 2020	None	$ 0.01	13,573,704

During the three months ended March 31, 2022, there were 3,442,567 warrants exercised resulting in the Company issuing 3,442,567 shares of common stock. There were no warrants exercised during the three months ended March 31, 2021.

10. Stock-Based Compensation

Award Incentive Plans

In August 2015, the Company's board of directors approved the 2015 Equity Incentive Plan ("2015 Plan"). In connection with the Company's IPO and the effectiveness of the 2018 Award Incentive Plan ("2018 Plan"), discussed below, the 2015 Plan terminated. The 92,815 shares of common stock that were then unissued and available for future issuance under the 2015 Plan became available under the 2018 Plan.

In September 2018, the Company's board of directors approved the 2018 Plan. Under the 2018 Plan, a total of 2,690,000 shares of common stock were initially reserved for issuance under the 2018 Plan, plus the number of shares remaining available for future awards under the 2015 Plan, as of the effective date of the 2018 Plan. The number of shares of common stock reserved for issuance under the 2018 Plan will automatically increase on January 1 of each year, beginning on January 1, 2019 and continuing through and including January 1, 2028, by 4% of the total number

of shares of the Company's outstanding stock on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors. The 2018 Plan provides, among others, for the grant of options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance bonus awards.

The maximum number of shares that may be issued upon the exercise of stock options under the 2018 Plan is 45,000,000.

The Company's board of directors has the authority to determine to whom options will be granted, the number of shares, the term, and the exercise price. If an individual owns stock representing 10% or more of the outstanding shares, the price of each share shall be at least 110% of the fair market value, as determined by the board of directors. Options granted have a term of up to 10 years and generally vest over a 4-year period with a straight-line vesting.

Material Features of the 2021 Employment Inducement Incentive Award Plan

In April 2021, the Company's board of directors adopted the 2021 Employment Inducement Incentive Award Plan (the "2021 Plan"), pursuant to Nasdaq Listing Rule 5635(c)(4). The principal purpose of the 2021 Plan is to enhance our ability to attract, retain and motivate employees who are expected to make important contributions to us by providing such individuals with equity ownership opportunities. Awards granted under the 2021 Plan are intended to constitute "employment inducement awards" under Nasdaq Listing Rule 5635(c)(4), and, as such, the 2021 Plan is intended to be exempt from the Nasdaq Listing Rules regarding shareholder approval of stock option and stock purchase plans. A total of 790,400 shares of our common stock ("Share Limit") were initially reserved for issuance under the 2021 Plan. The Share Limit may be increased by the Company's board of directors. The 2021 Plan provides for the grant of non-qualified stock options, restricted stock units, restricted stock awards, stock appreciation rights, and other stock-based and cash-based awards. The 2021 Plan does not provide for the grant of incentive stock options. Awards under the 2021 Plan may be granted to eligible employees who are either new employees or who are commencing employment with the Company or one of its subsidiaries following a bona fide period of non-employment with the Company, and for whom such awards are granted as a material inducement to commencing employment with the Company or one of its subsidiaries. Awards under the 2021 Plan may not be granted to the Company's consultants or non-employee directors.

The 2021 Plan is administered by our board of directors and, to the extent the Company's board of directors delegates its authority to it, the Company's compensation committee. In the event of a change in control in which the Company's successor refuses to assume or substitute any outstanding award under the 2021 Plan, the vesting of such award will accelerate in full. The Company's board of directors may terminate, amend, or modify the 2021 Plan at any time, provided that no termination or amendment may materially impair any rights under any outstanding award under the 2021 Plan without the consent of the holder.

Stock Option Activity

A summary of the 2018 Plan and 2021 Plan activity is as follows:

		Options Outstanding			
	Number of Shares Available for Issuance	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2021	3,459,187	5,107,335	$ 9.82	8.13	$ 17,153
Authorized	2,761,915	—	$ —		
Granted	(2,550,341)	2,200,168	$ 5.61		
Exercised	—	(73,713)	$ 0.87		
Cancelled	338,523	(302,640)	$ 10.21		
Balance at March 31, 2022	4,009,284	6,931,150	$ 8.56	8.53	$ 1,016
Vested and exercisable at March 31, 2022		2,329,666	$ 8.94	7.20	$ 996
Vested and expected to vest at March 31, 2022		6,076,920	$ 8.65	8.40	$ 1,013

For the three months ended March 31, 2022 and 2021, the total intrinsic value of stock option awards exercised was $0.3 million and $3.9 million, respectively, determined at the date of option exercise, and the total cash received upon exercise of stock options was not significant for either period. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying stock option awards and the estimated fair value of the common stock on the date of exercise.

As of March 31, 2022, $22.3 million of total unrecognized compensation cost related to non-vested employee and consultant options is expected to be recognized over a weighted-average period of 2.6 years. The total fair value of shares vested during the three months ended March 31, 2022 was $4.0 million.

Stock-based compensation expense and awards granted to non-employees were immaterial for the three months ended March 31, 2022 and 2021.

Restricted Stock Units

We have granted restricted stock unit awards under the 2018 Equity Plan. Our restricted stock unit awards have a term of up to 10 years and generally vest over a 1 or 2-year period. The following table summarizes our restricted stock unit activity during the three months ended March 31, 2022:

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding, unvested at December 31, 2021	708,800	$ 5.29
Issued	350,173	$ 5.46
Vested	(353,300)	$ 5.29
Canceled/Forfeited	(35,883)	$ 5.31
Outstanding, unvested at March 31, 2022	669,790	$ 5.38

Stock-Based Compensation Expense

Total stock-based compensation for all awards granted to employees, consultants and our 2018 Employee Stock Purchase Plan (“ESPP”), before taxes, is as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development expenses	$ 1,745	$ 1,481
General and administrative expenses	1,386	720
Total	$ 3,131	$ 2,201

11. Net Income (Loss) Per Common Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents.

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

	Three Months Ended March 31,	
	2022	2021
Numerator:		
Net income (loss)	$ (28,916)	$ 7,923
Denominator:		
Weighted-average common shares outstanding, basic	86,277,599	75,987,372
Effect of dilutive shares	—	1,476,984
Weighted-average common shares outstanding, diluted	86,277,599	77,464,356
Net income (loss) per share, basic	$ (0.34)	$ 0.10
Net income (loss) per share, diluted	$ (0.34)	$ 0.10

In December 2020, the Company issued and sold Warrants to purchase 27,480,719 shares of common stock at a nominal exercise price of $0.01 per share (see Note 9). The shares of common stock into which the Warrants may be exercised are considered outstanding for the purposes of computing earnings per share, because the shares may be issued for little or no consideration, they are fully vested and the Warrants are immediately exercisable upon their issuance date.

During a period of net loss, basic net loss per share is the same as diluted net loss per share, as the inclusion of all potential common shares outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	March 31,	
	2022	2021
Options issued and outstanding and ESPP shares issuable and outstanding	7,038,660	1,416,794
Restricted stock subject to future vesting	669,790	340
Total	7,708,450	1,417,134

12. Subsequent Events

The 2021 Plan Share Limit Increase

On April 21, 2022, the Company's board of directors approved a share limit increase of 700,000 shares under the 2021 Plan.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the condensed consolidated financial statements and notes thereto included elsewhere in this report, and our audited financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2021. This discussion and analysis, and other parts of this report, contain forward-looking statements, including, but not limited to, statements related to the potential of Gritstone's programs. Such forward-looking statements involve substantial risks and uncertainties that could cause the outcome of Gritstone's programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements, including interim results obtained may differ from those at completion of the studies and clinical trials. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including Gritstone's programs' clinical development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, Gritstone's ability to successfully establish, protect and defend its intellectual property and other matters that could affect the sufficiency of existing cash to fund Gritstone's operations. Our actual results could differ materially from those discussed in these forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to our business in general, see the section titled "Risk Factors". These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason.

Overview

We discover, develop, manufacture, and deliver next generation cancer and infectious disease vaccine candidates with the aim of improving patient outcomes and eliminating disease. The immune system sits at the nexus of many diseases, and manipulation of the immune system has enormous potential to drive transformational therapeutic and preventative benefits. Our approach seeks to generate a potent therapeutic or protective immune response by leveraging insights into the immune system's ability to recognize and destroy diseased cells and eliminate virally-infected cells. Our programs are built on two key platforms, the first being our proprietary Gritstone EDGE™ artificial intelligence platform, which enables us to identify antigens that can be recognized by the immune system with a high degree of accuracy. The second platform is our potent, flexible, vaccine platform, which we have engineered to deliver selected immunogens to the patient's immune system to drive the destruction of tumors or virally-infected cells. We accomplish this by leveraging our two proprietary vaccine vectors, self-amplifying mRNA (samRNA) and chimpanzee adenovirus (ChAd), which we have optimized to deliver immunogens selected by EDGE™ to the immune system. We utilize these "mix and match" vectors in a variety of ways, including as a heterologous prime-boost (one vector followed by the other) or homologous prime-boost (use the same vector twice). Our proprietary and synergistic technologies enable us to build robust and distinct pipelines in oncology and infectious disease. Additionally, our in-house manufacturing capabilities enable us to drive down both cost and production time, as well as maintain control over intellectual property and product quality of our products.

EDGE™ Antigen Discovery and T cell Target Identification

Our proprietary EDGE™ artificial intelligence platform has the ability to provide accurate identification of antigens that can be recognized by the immune system on tumor or virally-infected cells. In the case of tumor cells, mutations in tumor DNA provide a large set of altered (non-self) candidate protein fragments which can be assessed by EDGE™ with selection of high probability antigen targets (neoantigens) for inclusion in our vaccine candidates. In the case of pathogens, with a current focus on viruses, EDGE™ is used to analyze the DNA/RNA sequence of the pathogen with the goal of predicting which fragments of which genes will likely function as T cell antigens on the surface of virally-infected cells. Using EDGE™ in this way, we design the component of a vaccine candidate which contains the specific target antigens for administration to humans (immunogen), with the aim of generating strong immune responses to those antigens to achieve a desired biological effect. Such immune responses can be preventive (e.g., protecting against viral infections) or therapeutic (e.g., treating cancer by aiming to eliminate tumor cells through recognition of tumor neoantigens or treating virally induced disease by eliminating virus infected cells).

“Mix and Match” Delivery Systems

Having designed suitable immunogens with EDGE™, the next task is to embed the immunogen within a delivery system (vector) to stimulate the human host’s immune system and drive generation of T cells and/or neutralizing antibodies (nAbs) against the immunogen. The generation of CD8+ T cells has historically been challenging, and most vaccine vectors do not drive strong CD8+ T cell responses. This represents a key opportunity for us, and we have developed the following proprietary vectors that are designed to elicit B cell (neutralizing antibodies or nAbs) and T cell (including CD8+ T cell) responses: self-amplifying mRNA (samRNA) and chimpanzee adenovirus (ChAd). Immunogens encoded within these vectors are delivered to subjects, and immune responses to the chosen antigens can be measured. We believe these immune responses have the potential to lead to clinical benefit – either preventative (through the prevention of pathogen infection and its consequences (e.g., SARS-CoV-2 prophylactic vaccine) or therapeutic (e.g., solid tumor destruction or eradication of virally infected cells).

Self-amplifying mRNA (samRNA)

Our samRNA vector is based on a synthetic RNA molecule derived from a wild-type Venezuelan Equine Encephalitis Virus (VEEV) replicon with the goal of extending the duration and magnitude of immunogen expression to drive potent and durable immune responses. The samRNA is delivered in a lipid nanoparticle (LNP) formulation. Like traditional mRNA vaccines, samRNA vaccines use the host cell’s transcription system to produce target antigens to stimulate adaptive immunity. Unlike traditional mRNA, samRNA has an inherent ability to replicate by creating copies of the original strand of RNA once it is in the cell. Potential benefits of samRNA may include extended duration and magnitude of antigen expression, strong and durable induction of neutralizing antibody and T cell immunity (CD4+ and CD8+), dose sparing, and a refrigerator stable product.

The samRNA platform is becoming established as a key asset for Gritstone. During the 2022 American Association for Cancer Research (AACR) Annual Meeting, we presented clinical data from our SLATE and GRANITE programs including the identification and selection of an optimal dosing regimen for our novel samRNA vector which demonstrates more robust immune responses at lower doses (poster presentation title: “Lower doses of self-amplifying mRNA drive superior neoantigen-specific CD8+ T cell responses in cancer patients versus high doses”). Our preclinical and clinical studies to date in the CORAL program demonstrate the potential overall potency and dose sparing opportunity of samRNA in viral diseases.

The success of first-generation mRNA vaccines for SARS-CoV-2 (Comirnaty® and Spikevax) has validated mRNA as a vaccine technology, and we believe the samRNA vector has the potential to offer key benefits over mRNA, including dose sparing and more potent CD8+ T cell induction, within both oncology and viral diseases.

Chimpanzee Adenovirus (ChAd)

Chimpanzee Adenoviral (ChAd) vectors have been utilized in clinical studies in infectious disease and oncology over the last 20 years, and have been demonstrated to be well tolerated and effective at generating rapid and substantial CD4+ and CD8+ T cell responses. Additionally, ChAd vectors can induce B cell immune responses, i.e., elicit nAbs.

In-house Manufacturing

We manufacture our products at our own fully-integrated current good manufacturing practice (cGMP) biomanufacturing facilities. Our ability to control the manufacturing of high-quality tumor-specific immunotherapy products, and scale production, if early data are positive, is critical for efficient clinical development of our vaccine candidates and commercialization. To control the critical steps in the production of our vaccine candidates, we have invested significant resources in our sequencing lab located in Cambridge, Massachusetts and our biomanufacturing facility located in Pleasanton, California.

Our in-house manufacturing know-how also contributes to our translational science and optimization of our production candidates. Through our work, we gain insights from “bench to manufacturing to bedside” and back. We have processes in place to translate such insights across functions and systems to optimize antigen cassette design, dose and vaccine regimen to induce differentiated immune response.

The table below summarizes key information about our ongoing clinical trials.

Program	Phase	Status	Indication(s)	Collaborator	Commercial Rights
GRANITE	1/2	Enrollment Complete; Treatment Ongoing	Early stage & advanced solid tumors	NA	Gritstone
GRANITE	2/3	Enrolling for inclusion	MSS-CRC* first line maintenance	NA	Gritstone
GRANITE	2	Enrolling for inclusion	MSS-colon cancer adjuvant	NA	Gritstone
SLATE	1/2	Complete	p53, KRAS Advanced Solid Tumors	NA	Gritstone
SLATE	2	Enrolling	$KRAS^{mut}$	NA	Gritstone
CORAL	1	Enrolling	COVID-19 naïve & booster	NIAID, IDCRC	Gritstone
CORAL	1	Enrolling	COVID-19 booster	NA	Gritstone
CORAL	1	Enrolling	COVID-19 immunocompromised	NA	Gritstone
CORAL	1	Enrolling	COVID-19 in South Africa (naïve, convalescent, HIV+)	CEPI	Gritstone
HIV	1	4Q 2021 IND Cleared	HIV treatment/cure	Gilead Sciences	Gilead**

* MSS-CRC = microsatellite stable colorectal cancer
** Gilead is responsible for conducting a Phase 1 study

Oncology Programs

Neoantigen Derived Immunotherapy

Neoantigens are a newly-identified class of targets for cancer immunotherapy and have been validated in cancer patients as potentially the most critical T cell targets. These neoantigens comprise short, tumor-specific, mutated peptide sequences presented on cancer cells, referred to as tumor-specific neoantigens (TSNA), or fragments of viral proteins displayed upon the surface of cells infected by virus. Accurate identification of these critical protein fragments a priori is not a simple undertaking. Evidence suggests that when a solid tumor patient responds to anti-PD1 antibody therapy, they do so because T cells that recognize TSNA are activated. Neoantigens can be classified as either patient-specific, meaning each patient has their own unique neoantigens, or shared, whereby some common driver mutations are presented on the tumor cell surface of multiple patients. We believe that our EDGE™ platform leads the field in TSNA identification. A core challenge in TSNA prediction is that T cells recognize short mutant peptides presented on the surface of tumor cells by human leukocyte antigen (HLA molecules, which are platform-like structures that vary profoundly across individuals. Prediction of TSNA, therefore, must be tailored to each individual, comprehending their own tumor mutations and their HLA types.

We are developing a portfolio of vaccine-based cancer immunotherapy product candidates using a heterologous prime (ChAd)/boost (samRNA) approach aimed at the highly targeted activation of tumor-specific T cells in solid tumors. Our two clinical-stage programs (GRANITE, which is “individualized” and SLATE, which is “off-the-shelf”) aim to induce a substantial neoantigen-specific CD8+ T cell response using neoantigen-containing immunotherapies. We have designed our personalized vaccine-based immunotherapy candidates such that oncologists will not have to alter their treatment practices, and we believe that this will extend the utility of our product candidates, if approved, into the community setting and not limit their use to scarce centers of excellence. GRANITE patients receive product candidate made specifically for them, based upon their tumor DNA/RNA sequence. In contrast, SLATE patients are selected to carry both a particular mutation and the matching HLA type. Nevertheless, we have observed cytotoxic T cell responses to multiple administered TSNA and early signs of clinical benefit in both of these oncology product candidates. The vaccine-based immunotherapy regimens consist of administration of the TSNA-containing vectors (vaccines) together with checkpoint inhibitors (systemic anti-PD1 antibody and low-dose subcutaneous anti-CTLA4 antibody).

GRANITE Individualized Vaccine Program for Solid Tumors

Our first oncology product candidate, GRANITE, is an individualized neoantigen-based immunotherapy. We utilize our in-house sequencing capabilities on the tumor sample and then apply our proprietary EDGE™ platform to derive a set of predicted TSNA likely to be presented on the patient’s tumor. Using these TSNA, we design a highly potent individualized immunotherapy candidate containing the relevant neoantigens to be administered by simple

intramuscular injection. We have designed each of our tumor-specific vaccine-based immunotherapy candidates such that oncologists will not have to alter their treatment practices, and we believe this approach would extend the utility of our product candidates into the community oncology setting and not limit their use to scarce centers of excellence. We believe that, thanks to its design, our tumor-specific vaccine-based immunotherapy candidate has the potential to expand the efficacy of immunotherapy into broader patient populations. GRANITE was granted Fast Track designation by the FDA for the treatment of microsatellite stable colorectal cancer (MSS-CRC).

We have completed enrollment (treatment ongoing) for a Phase 1/2 clinical trial for GRANITE in combination with checkpoint inhibitors for patients with MSS-CRC who have progressed on FOLFOX/FOLFIRI therapy and in patients with gastro-esophageal (GEA) cancer who have progressed on chemotherapy. We presented updated interim efficacy, immunogenicity and safety data from this GRANITE Phase 1/2 study during the European Society of Medical Oncology (ESMO) congress in September 2021. As of the August 5, 2021 data cut-off date, GRANITE immunotherapy was generally well tolerated in 26 patients treated in the study with metastatic solid tumors largely focused on MSS-CRC and GEA and showed no dose limiting toxicities, consistent and potent immunogenicity (CD8+ neoantigen-specific T cell induction in all subjects), in addition to tumor lesion size reductions and molecular responses as measured by reduction in circulating tumor DNA (cDNA). As of January 5, 2022 (the most recent cutoff date from which data was announced for this study), 6 of 12 MSS-CRC patients treated in such GRANITE trial, who were alive at the time of our ESMO 2021 data presentation on September 17, 2021, remained alive, including 4 patients alive after at least 12 months. Additionally, the correlation between a decrease in ctDNA and improved overall survival continued to be observed. We have delivered several presentations at medical meetings demonstrating the correlation between circulating tumor DNA (ctDNA) and overall survival, including at the 2022 AACR Annual Meeting (presentation title: "*Comprehensive ctDNA monitoring provides early signal of clinical benefit with a novel personalized neoantigen directed immunotherapy for late-stage cancer patients*").

Based on the signals of activity observed in the GRANITE Phase 1/2 study, especially in MSS-CRC, we subsequently launched two new studies for patients with MSS-CRC. The first study (GRANITE-CRC-1L, NCT05141721), which has registrational intent and has been discussed with the FDA, is a Phase 2/3 study evaluating GRANITE as a maintenance treatment in patients with newly diagnosed, metastatic MSS-CRC who have completed FOLFOX-bevacizumab induction therapy. In support of this study, we entered into a clinical trial collaboration and supply agreement with F. Hoffman-La Roche Ltd to evaluate the safety and tolerability of GRANITE in combination with TECENTRIQ (atezolizumab). The second study is a separate randomized Phase 2 trial evaluating GRANITE in the adjuvant setting (GRANITE-CRC-ADJUVANT) in patients with stage II/III colon cancer who have minimal residual disease based on the detection of circulating tumor after definitive surgery. Enrollment for inclusion in both of these studies has commenced (GRANITE-CRC-ADJUVANT and GRANITE-CRC-1L). Initial data from the GRANITE-CRC-1L trial is expected in the second half of 2023.

SLATE "Off the shelf" Vaccine Program for Solid Tumors

Our off-the-shelf, TSNA-directed immunotherapy product candidate, SLATE, utilizes the same heterologous prime-boost approach. However, SLATE contains a fixed cassette with TSNA that are shared across a subset of cancer patients rather than a cassette unique to an individual patient, which distinguishes it as a potential off-the-shelf alternative candidate to GRANITE. The first version of SLATE (SLATE v1) was studied in a Phase 1/2 study, in collaboration with Bristol-Myers Squibb, in 26 patients with metastatic solid tumors, most of whom had KRAS-mutant tumors largely focused on non-small cell lung cancer (NSCLC), MSS-CRC, and pancreatic ductal adenocarcinoma. In this initial study, which was focused on KRAS and p53 mutations, SLATE v1 demonstrated induction of CD8+ T cells against multiple KRAS driver mutations, and greatest activity was seen in a subset of NSCLC patients with the KRASmut G12C mutations. Although these initial outcomes were very promising, we believed we could further optimize the SLATE candidate to further maximize potential clinical benefit.

Subsequently, we developed a next generation, optimized SLATE candidate, SLATE-KRAS, (formerly referred to as SLATE v2) that exclusively includes epitopes from mutated KRAS and exhibited immunogenic superiority over v1 in human HLA-transgenic mice. SLATE-KRAS is now in Phase 2 testing (under the same IND as SLATE v1) in patients with advanced NSCLC and CRC. We expect to release initial data from the Phase 2 study of SLATE-KRAS, in the second half of 2022.

In an oral presentation at the 2022 AACR Annual Meeting, we presented early signals from the ongoing Phase 2 study which support the potential of SLATE-KRAS to drive stronger CD8+ T cell responses to mutant KRAS than our original candidate, SLATE v1 (Presentation title: "*Optimization of shared neoantigen vaccine design to increase vaccine potency: From bench to bedside and back*"). As part of our presentation, we also discussed how translational

immunology data enabled iterative development of SLATE-KRAS based on the previous phase 1 study. Our long-term vision is to continue optimizing this immunotherapy candidate to include other antigen classes to both broaden addressable patient population and also drive multiple antigens per patient.

Infectious Disease Programs

In early 2021, we expanded our programs to include infectious diseases with the announcements of a second-generation vaccine program against SARS-CoV-2 (CORAL) and a therapeutic vaccine candidate designed to treat and potentially cure human immunodeficiency virus (HIV) infection. Our infectious disease programs aim to deliver vaccine candidates that drive both B cell and T cell immunity with the potential to provide either a protective or therapeutic effect across a broad array of viral diseases. This approach has demonstrated the ability to generate robust CD8+ T cells and neutralizing antibodies against SARS-CoV-2 in multiple preclinical and clinical studies and is being evaluated against multiple other pathogens in Gritstone-owned and partnered studies.

CORAL – Second Generation COVID-19 Vaccine Program

Our CORAL program is a second-generation SARS-CoV-2 vaccine platform delivering spike and additional SARS-CoV-2 T cell epitopes, which we believe could offer the potential for more durable protection and broader immunity against SARS-CoV-2 variants. Within this program, we are utilizing an optimized samRNA vaccine candidate that we developed and believe is differentiated from first-generation SARS-CoV-2 vaccines. Differentiating characteristics of samRNA include the potential for increased antigen expression relative to non-replicating mRNA and for potent CD8+ T cell responses against numerous T cell targets. SamRNA also holds the potential for dose sparing and refrigerator stability, both of which are not currently provided by first-generation mRNA vaccines. The program is supported by key relationships with the Gates Foundation, the National Institute of Allergy and Infectious Disease (NIAID), the Coalition for Epidemic Preparedness Innovations (CEPI), and through a license agreement with the La Jolla Institute for Immunology (LJI). We believe this “T cell-enhanced samRNA” approach could also represent a first step toward developing a pan-coronavirus vaccine.

We have conducted preclinical studies demonstrating that our SARS-CoV-2 vaccine candidate induced significant and sustained levels of neutralizing antibodies and T cells against the Spike protein, plus a broad T cell response against epitopes from multiple viral genes outside of Spike. We published data from one of these studies, a non-human primate challenge study (NHP Challenge Study), in November 2021.

We are currently evaluating five distinct SARS-CoV-2 product candidates across four different clinical trials containing Spike plus additional non-Spike T cell epitope (TCE) sequences (and also full-length nucleocapsid). These studies include homologous and heterologous prime-boost regimens. All four of these studies are ongoing, and data from all are expected in the second half of 2022.

CORAL-BOOST (GO-009, NCT05148962)

Product Candidate	Construct
GRT-R910 (samRNA)	SWT-TCE5

In September 2021, we initiated a Gritstone-sponsored Phase 1 dose escalation boost study evaluating our samRNA SARS CoV-2 vaccine candidate, GRT-R910, which includes construct Swt-TCE5 as a single boost dose in healthy adults ≥60 years of age who have previously been vaccinated with the first-generation AstraZeneca SARS-CoV-2 vaccine. Safety data for the first cohort of participants who received a 10µg dose of GRT-R910 showed no grade 3 or 4 events or serious adverse events reported. In this same cohort, robust CD8+ T cell responses to conserved TCEs from SARS-CoV-2 were induced, including Nucleoprotein (N), Membrane (M), and ORF3a, which have been shown to offer T cell targets in convalescent individuals. A boost in pre-existing Spike-specific T cell responses was observed. Furthermore, although this Phase 1 study did not include a head-to-head comparison against other vaccine candidates, potent neutralizing antibodies against Spike (geometric mean titer of 2,370 using standardized pseudovirus neutralizing assay) were observed at levels consistent with published data from first-generation mRNA vaccines in a similar clinical context (CORAL-BOOST study; Munro et al Lancet 2021). Initially, a single institution study, this boost study is being amended to investigate the performance of a homologous prime and boost dose of GRT-R910 in adults ≥ 18 years of age who have previously received an authorized vaccine (either mRNA or adenovirus-based).

CORAL-NIH (NCT04776317)

Product Candidate	Construct
GRT-C907 (ChAd)/ -R908 (samRNA)	SWT
GRT- C909 (ChAd)/ -R910 (samRNA)	SWT-TCE5

We are collaborating with NIAID on a Phase 1 clinical trial which is being sponsored and executed by the National Institute of Allergy and Infectious Disease (NIAID), is ongoing in the United States. The trial was amended to evaluate a CORAL platform candidate as a boost to first- generation SARS-CoV-2 vaccines and is currently evaluating increasing doses of samRNA (in adults 18-60 and >60 years of age) and ChAd (>60 years of age only).

CORAL-IMMUNOCOMPROMISED (GO-011, NCT04776317)

Product Candidate	Construct
GRT-C909 (ChAd)/ -R910 (samRNA)	SWT-TCE5

We have initiated a Gritstone-sponsored Phase 1 trial in the United Kingdom evaluating homologous (ChAd/ChAd) and heterologous (ChAd/samRNA) prime-boost regimens containing Swt-TCE5 in patients being treated with B-cell depleting therapies for hematological malignancies or multiple sclerosis, utilizing GRT-C909 and GRT-R910. The majority of patients receiving these therapies mount poor immunologic responses to first generation vaccines and are at higher risk for severe infection from SARS-CoV-2. As these patients do not have sufficient B cell function, we believe vaccines like GRT-C909 and GRT-R910 that are designed to induced robust T cell responses may afford greater protection against SARS-CoV-2 than the first-generation vaccines.

CORAL-CEPI (GO-012)

Product Candidate	Construct
GRT-R914 (samRNA)	SBeta-TCE9
GRT-R912 (samRNA)	SBeta-N-TCE11
GRT-R918 (samRNA)	SOmicron-N-TCE11

We have initiated a large Phase 1 study in South Africa with up to $25.6 million in funding support from CEPI. The study is intended to evaluate our samRNA platform in multiple populations. Two samRNA vaccines (GRT-R912 and GRT-R914) have been engineered using the Spike protein from the SARS-CoV-2 Beta variant (that contributed to the large second wave of SARS-CoV-2 infections in South Africa) with two different TCE expression cassettes and more recently a samRNA vaccine candidate (GRT-R918) that has been engineered using the Spike protein from the SARS-CoV-2 Omicron variant (contributing to the ongoing fourth wave of SARS-CoV-2 infections in South Africa). GRT-R912 and GRT-R914 are being evaluated as a homologous prime/boost in healthy adults <65 years of age who have neither been previously vaccinated against SARS-CoV-2 or infected with SARS-CoV-2 and as a single boost in healthy adults <65 years of age who previously were infected with SARS-CoV-2. Furthermore, GRT-R912 and GRT-R914 will be evaluated in persons living with HIV, an underserved population with 1st generation vaccines who may be at greater risk of serious infections from SARS-CoV-2. GRT-R918 will be investigated as a homologous prime/boost in healthy adults ≥ 18 years of age regardless of vaccination status or prior infection with SARS-CoV-2 to evaluate whether an omicron-variant specific vaccine may be more effective than a beta-variant specific vaccine.

HIV Vaccine Collaboration with Gilead Sciences

In January 2021, we entered into a collaboration, option and license agreement with Gilead Sciences, Inc. (Gilead) to research and develop a vaccine-based immunotherapy for HIV. Together, we plan to develop an HIV-specific therapeutic vaccine using our proprietary prime-boost vaccine platform, comprised of samRNA and adenoviral vectors, with antigens developed by Gilead. Under the terms of the agreement, Gilead invested $60.0 million, consisting of a $30.0 million upfront cash payment and a $30.0 million equity investment at the closing. Gilead will be responsible for conducting a Phase 1 study for the HIV-specific therapeutic vaccine and holds an exclusive option under the collaboration to obtain an exclusive license to develop and commercialize the HIV-specific therapeutic vaccine beyond Phase 1. We are also eligible to receive up to an additional $725.0 million if the option is exercised and if certain clinical, regulatory and commercial milestones are achieved, as well as mid-single-digit to

low double-digit tiered royalties on net sales upon commercialization. Gritstone and Gilead received IND clearance for this program in December 2021.

COVID-19 Update

The COVID-19 pandemic has placed strains on the providers of healthcare services, including the healthcare institutions where we conduct our clinical trials. These strains have resulted in institutions prohibiting the initiation of new clinical trials, slowing or halting enrollment in existing trials and restricting the on-site monitoring of clinical trials. Our operations have not been materially impacted by the COVID-19 pandemic. However, we have experienced slowing of patient recruitment and sample collection in our ongoing clinical trials. Additionally, as a result of the COVID-19 pandemic, competition for potential patients in our trials may be further exaggerated as a result of multiple clinical site closures. To date, the COVID-19 pandemic has not materially affected our supply chain or production schedule, but further escalation of the health crisis has the potential to cause delays in our supply chain and manufacturing operations, which could materially adversely impact our business.

We have not experienced any material disruptions in our supply chain necessary to conduct our ongoing clinical trials. In response to the COVID-19 pandemic, we have implemented heightened health and safety measures designed to comply with applicable federal, state and local guidelines. In particular, we transitioned to a flexible work environment, allowing employees who can work from home effectively to do so. We are further supporting all of our employees by leveraging virtual meeting and messaging technology and by encouraging employees to follow local health authority guidance. As the pandemic continues to evolve, we may need to undertake additional actions that could impact our operations if required by applicable laws or regulations or if we determine such actions to be in the best interests of our employees.

Components of Our Operating Results

Collaboration and Grant Revenue

To date, we have not generated any revenue from product sales, and we do not expect to generate any revenue from product sales for the foreseeable future. For the three months ended March 31, 2022 and 2021, we recognized $7.2 million and $39.7 million, respectively, of revenue from the 2seventy Agreement, the Gilead Collaboration Agreement, another small collaboration agreement and the grant agreements with CEPI and the Gates Foundation. See Note 8 to our condensed consolidated financial statements for additional information.

In the future, we expect to continue to recognize revenue from the 2seventy Agreement and the Gilead Collaboration Agreement and may generate revenue from product sales or other collaboration agreements, strategic alliances and licensing arrangements. We expect our revenue to fluctuate from quarter-to-quarter and year-to-year as a result of the timing and amount of license fees, milestones, reimbursement of costs incurred and other payments and product sales, to the extent that any are successfully commercialized. If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Operating Expenses

Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities, including conducting preclinical studies, manufacturing development efforts and related development activities for our product candidates.

Research and development activities account for a significant portion of our operating expenses. Research and development costs are expensed as incurred. These costs include:

- External research and development expenses, including:
- expenses incurred under arrangements with third parties, including clinical research organizations, or CROs, preclinical testing organizations, CMOs, academic and non-profit institutions and consultants;
- fees related to our license agreements;
- Internal research and development expenses, including:
- headcount-related expenses, including salaries, payroll taxes, benefits, non-cash stock-based compensation and travel, for employees contributing to research and development activities, including the costs associated with the development of our EDGE™ platform; and
- Other expenses, which include direct and allocated expenses for laboratories, facilities and other costs..

Pursuant to our Arbutus License Agreement, Arbutus granted us a worldwide, exclusive license to certain technology of Arbutus, including Arbutus' portfolio of proprietary and clinically-validated LNP products and associated intellectual property, as well as technology transfer of Arbutus' manufacturing know-how. During the three months ended March 31, 2022 and 2021, we had no research and development expense under the agreement.

Pursuant to our 2020 Genevant License Agreement, Genevant granted us exclusive license rights under certain intellectual property related to Genevant's LNP technology for a single indication, and we agreed to pay Genevant an initial payment of $2.0 million, and up to an aggregate of $71.0 million in specified development, regulatory, and commercial milestones, and low to mid-single digit royalties on net sales of licensed products. The upfront payment of $2.0 million was included in research and development expenses during 2020. In March 2022, a milestone in the amount of $1.0 million was met, which was included in research and development expense for the three months ended March 31, 2022.

Pursuant to our 2021 Genevant License Agreement, we obtained a nonexclusive license to Genevant's LNP technology to develop and commercialize self-amplifying RNA, or samRNA, vaccines against SARS-CoV-2, the virus that causes COVID-19. Under the 2021 Genevant License Agreement, we made a $1.5 million upfront payment to Genevant, and Genevant is eligible to receive from us up to $141.0 million in contingent milestone payments per product, plus certain royalties on future product sales or licensing (or, in certain scenarios and subject to certain conditions, in lieu of these milestones and royalties Genevant would receive a percentage of amounts we receive from sublicenses). In March 2021, a milestone was met following the initial patient treatment in the Phase 1 clinical trial conducted through the NIAID-supported IDCRC. Both the $1.5 million upfront and $1.0 million milestone payments were recorded as research and development expense for the three months ended March 31, 2021. No research and development expense was recorded for the three months ended March 31, 2022.

We expect our research and development expenses to increase substantially in the future as we continue to advance our product candidates into and through clinical studies and pursue regulatory approval. Conducting the necessary clinical studies to obtain regulatory approval is costly and time-consuming, and such clinical studies generally become larger and more costly to conduct as they advance into later stages. The successful development of our product candidates is highly uncertain. The actual probability of success for our product candidates may be affected by a variety of risks and uncertainties associated with drug development, including those set forth in the section entitled "Risk Factors" included in Part II, Section 1A and elsewhere in this report.

The following table summarizes our research and development expenses by program and category (in thousands):

	Three Months Ended March 31,	
	2022	2021
GRANITE program external expenses	$ 2,698	$ 2,564
SLATE program external expenses	796	1,102
CORAL program external expenses	3,005	730
Other program external research and development expenses	6,702	8,215
Personnel-related expenses [(1)]	10,587	8,035
Other unallocated research and development expenses	4,411	4,210
Total research and development expenses	$ 28,199	$ 24,856

(1) Personnel-related expenses include stock-based compensation expense of $1.7 million and $1.5 million, respectively, for the three months ended March 31, 2022 and 2021, respectively.

We do not track internal related expenses on a program-by-program basis, because our research and development employees and infrastructure resources are utilized across our development programs.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and related costs, including payroll taxes, benefits, non-cash stock-based compensation and travel. Other general and administrative expenses include legal costs of pursuing patent protection of our intellectual property, and professional service fees for auditing, tax and general legal services. We expect our general and administrative expenses to continue to increase in the future as we expand our operating activities and prepare for potential commercialization of our current and future product candidates, increase our headcount and support our operations as a public company, including increased expenses related to legal, accounting, regulatory and tax-related services associated with maintaining compliance with requirements of the Nasdaq Global Select Market and the SEC, directors and officers liability insurance premiums and investor relations activities. Allocated expenses consist of rent expenses related to our office and research and development facilities, depreciation and other allocated costs not otherwise included in research and development expenses.

Interest Income, Net

Interest income, net, consists primarily of interest income and investment income earned on our cash, cash equivalents and marketable securities.

Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2021

The following table sets forth the significant components of our results of operations (in thousands):

	Three Months Ended March 31,		
	2022	2021	Change
Revenues:			
Collaboration and license revenues	$ 4,745	$ 39,693	$ (34,948)
Grant revenues	2,446	—	2,446
Total revenues	7,191	39,693	(32,502)
Operating expenses:			
Research and development	28,199	24,856	3,343
General and administrative	7,955	6,941	1,014
Total operating expenses	36,154	31,797	4,357
Income (loss) from operations	(28,963)	7,896	(36,859)
Interest income, net	47	27	20
Net income (loss)	$ (28,916)	$ 7,923	$ (36,839)

Collaboration and License and Grant Revenues

Collaboration and license revenues from our collaboration arrangements and grant revenues were $7.2 million and $39.7 million for the three months ended March 31, 2022 and 2021, respectively. During the three months ended March 31, 2022, we recognized $4.0 million in collaboration revenue related to the 2seventy Agreement, $0.7 million in collaboration revenue related to the Gilead Collaboration Agreement, $2.2 million in grant revenue from the CEPI Funding Agreement, and $0.2 million in grant revenue from the Gates Foundation. The amount of collaboration revenue recognized related to the 2seventy Agreement during the three months ended March 31, 2022 included a cumulative catch-up adjustment increasing contribution revenue by $3.5 million due to revisions to estimated costs to complete the remaining performance obligation. During the three months ended March 31, 2021, we recorded $38.6 million in license revenue and $0.3 million in collaboration revenue related to the Gilead Collaboration Agreement and $0.7 million in collaboration revenue related to the 2seventy Agreement. See Note 8 to our condensed consolidated financial statements for additional information.

Research and Development Expenses

Research and development expenses were $28.2 million and $24.9 million for the three months ended March 31, 2022 and 2021, respectively.

The increase of $3.3 million for the three months ended March 31, 2022 compared to the three months ended March 31, 2021 was primarily due to increases of $2.6 million in personnel-related expenses, $3.0 million in outside services, and $0.5 million in facilities related costs, offset by decreases of $1.0 million in laboratory supplies and $1.8 million in milestone and license payments.

General and Administrative Expenses

General and administrative expenses were $8.0 million for the three months ended March 31, 2022 compared to $6.9 million for the three months ended March 21, 2021. The increase of $1.1 million was primarily attributable to increases of $1.4 million in personnel-related expenses and $0.2 million in facilities related costs, offset by a decrease of $0.5 million in outside services.

Interest Income, Net

Interest income, net was immaterial for the three months ended March 31, 2022 and 2021. The income for both periods represents interest and investment income from cash, cash equivalents and marketable securities.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily through sales of our convertible preferred stock, sales of our common stock in public offerings and under our 2019 ATM Offering Program, private placements of our common stock and pre-funded warrants, and our collaborations, including with the receipt of proceeds under the 2seventy Agreement and the Gilead Collaboration Agreement, and non-dilutive grants from various nonprofit organizations. As of March 31, 2022, we had cash, cash equivalents, and marketable securities of $172.2 million and an accumulated deficit of $430.3 million, compared to cash, cash equivalents, and marketable securities of $206.3 million and an accumulated deficit of $401.4 million as of December 31, 2021. We expect that our cash, cash equivalents, and marketable securities as of March 31, 2022 will enable us to fund our current and planned operating expenses and capital expenditures for at least the next 12 months from the date of the filing of this report.

In October 2019, we filed the 2019 Shelf Registration Statement, covering the offering of up to $250.0 million of various equity and debt securities, including the sale and issuance of up to $75.0 million worth of shares of our common stock under the 2019 ATM Offering Program. Through March 31, 2022, we have received aggregate proceeds from our 2019 ATM Offering Program of $50.0 million, net of commissions and offering costs. We have $22.9 million available under our 2019 ATM Offering Program as of March 31, 2022.

In December 2020, we completed the First PIPE Financing, pursuant to which we sold (i) an aggregate of 5,543,351 shares of common stock at a per share purchase price of $3.34, (ii) pre-funded warrants to purchase an aggregate of 27,480,719 shares of common stock at a price per warrant share of $3.34 per share of common stock (of

which $3.33 per share was pre-paid by each purchaser), and (iii) an aggregate of 4,043,127 shares of common stock at a per share purchase price of $3.71. In connection with the First PIPE Financing, we received $125.0 million in aggregate gross cash proceeds and incurred related costs of $5.7 million.

In September 2021, we completed the Second PIPE Financing, pursuant to which we sold an aggregate of 5,000,000 shares of common stock at a per share purchase price of $11.00. In connection with the SECOND PIPE Financing, we received $55.0 million in aggregate gross cash proceeds and incurred related costs of $2.3 million.

In February 2021, we received a non-refundable upfront payment of $30.0 million under the Gilead Collaboration Agreement and $30.0 million under the Gilead Stock Purchase Agreement.

In September 2021, we received an upfront payment of $11.3 million under the CEPI Funding Agreement.

In March 2022, we filed the 2022 Shelf Registration Statement, covering the offering of up to $250.0 million of various equity and debt securities, including the sale and issuance of up to $100.0 million worth of shares of our common stock under the 2022 ATM Offering Program. As of March 31, 2022, we have not received any proceeds from our 2022 ATM Offering Program and have $100.0 million available thereunder.

Future Funding Requirements

We do not expect positive cash flows from operations in the foreseeable future. Historically, we have incurred operating losses as a result of ongoing efforts to develop our cancer immunotherapy candidates, including conducting ongoing research and development, clinical and preclinical studies and providing general and administrative support for these operations. We do not have any products approved for sale, and we do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our current and future product candidates and/or enter into additional significant collaboration or grant agreements with third parties, and we do not know when, or if, either will occur. We expect to continue to incur net operating losses for at least the next several years and we expect the losses to increase as we advance our CORAL, GRANITE, and SLATE programs, as well as any future product candidates, through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization, continue our research and development efforts and invest in our manufacturing facility. We are subject to all the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Moreover, we incur substantial costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of revenue from the commercialization of immunotherapy product candidates or from additional significant collaboration or license agreements with third parties, if ever, we expect to finance our future cash needs through private and public equity offerings, including our ATM Offering Program, debt financings, and potential future collaboration, license and development agreements. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our current or future product candidates. If we raise additional funds by issuing equity or convertible debt securities, it could result in dilution to our existing stockholders and increased fixed payment obligations. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term, but we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. Any of the foregoing could significantly harm our business, financial condition and prospects.

Since our inception, we have incurred significant losses and negative cash flows from operations. We have an accumulated deficit of $430.3 million through March 31, 2022. We expect to incur substantial additional losses in the future as we conduct and expand our research and development activities. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to enable us to fund our projected operations through at least the next twelve (12) months from the date of this report. We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and

commercialization of product candidates, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of developing our product candidates, and of conducting preclinical studies and clinical trials, including our clinical trials for GRANITE, SLATE and CORAL;
- potential delays in our ongoing clinical trials as a result of the COVID-19 pandemic;
- the timing of, and the costs involved in, obtaining regulatory approvals for our oncology and infectious disease immunotherapy product candidates; in particular, any costs incurred in connection with any future regulatory requirements that may be imposed by the FDA or foreign regulatory bodies;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing and amount of any milestone, royalty or other payments we are required to make pursuant to any current or future collaboration or license agreements;
- the cost of manufacturing our product candidates we successfully commercialize, including the cost of scaling up our internal manufacturing operations;
- the cost of building a sales force in anticipation of product commercialization;
- the cost of commercialization activities, including building a commercial infrastructure, marketing, sales and distribution costs;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the costs to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the timing, receipt and amount of sales of any future approved products, if any.

A change in the outcome of any of these or other variables with respect to the development of any of our current and future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will need additional funds to meet operational needs and capital requirements associated with such operating plans.

Cash Flows

The following table sets forth a summary of the primary sources and uses of cash for each of the periods presented below (in thousands):

	Three Months Ended March 31,	
	2022	2021
Cash provided by (used in) operating activities	$ (33,451)	$ 10,654
Cash provided by (used in) investing activities	7,634	(89,600)
Cash provided by (used in) financing activities	(917)	17,395
Net decrease in cash and cash equivalents	$ (26,734)	$ (61,551)

Cash Provided by (Used in) Operating Activities

During the three months ended March 31, 2022, cash used in operating activities was $33.5 million, which consisted of net loss of $28.9 million, adjusted by non-cash charges of $7.2 million and net changes in our operating assets and liabilities of $11.8 million. The non-cash charges consisted primarily of depreciation and amortization expense of $1.6 million, stock-based compensation of $3.1 million, non-cash operating lease expense of $2.3 million

and net amortization of premiums and discounts on marketable securities of $0.2 million. The change in our operating assets and liabilities was primarily due to decreases of $6.5 million in deferred revenue, $2.6 million in accrued compensation, $2.0 million in lease liability and an increase of $3.3 million in prepaid expenses and other current assets, offset by an increase of $1.9 million in accounts payable and decrease of $0.8 million in deposits and other long-term assets.

During the three months ended March 31, 2021, cash provided by operating activities was $10.7 million, which consisted of net income of $7.9 million, adjusted by non-cash charges of $5.8 million and net changes in our operating assets and liabilities of $3.0 million. The non-cash charges consisted primarily of depreciation and amortization expense of $1.6 million, stock-based compensation of $2.2 million and non-cash operating lease expense of $1.9 million. The change in our operating assets and liabilities was primarily due to increases of $1.6 million in accounts payable and $0.5 million in accrued research and development, offset by decreases of $2.0 million in lease liability, $2.5 million in accrued compensation, $0.5 million in deferred revenue and an increase of $0.2 million in prepaid expenses and other current assets.

Cash Provided by (Used in) Investing Activities

During the three months ended March 31, 2022, cash provided by investing activities was $7.6 million, which consisted of $26.5 million in proceeds from the maturity of marketable securities and $11.2 million from sales of marketable securities, offset by $28.3 million in purchases of marketable securities and $1.8 million of capital expenditures to purchase property and equipment.

During the three months ended March 31, 2021, cash used in investing activities was $89.6 million, which consisted of $89.6 million in purchases of marketable securities and $1.0 million of capital expenditures to purchase property and equipment, offset by $1.0 million in proceeds from the maturity of marketable securities.

Cash Provided by (Used in) Financing Activities

During the three months ended March 31, 2022, cash used in financing activities was $0.9 million, which primarily consisted of $0.9 million in tax withholding on vesting of restricted stock units and $0.1 million in payment of financing costs, offset by $0.1 million in proceeds from the issuance of common stock from option and warrant exercises.

During the three months ended March 31, 2021, cash provided by financing activities was $17.4 million, which primarily consisted of $21.2 million in proceeds from the issuance of common stock under the Gilead Stock Purchase Agreement, $0.3 million in proceeds from the issuance of common stock under the employee stock purchase plan and $1.8 million in proceeds from the exercise of stock options, offset by $5.9 million in financing and offering costs.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements, as defined under SEC rules.

Contractual Obligations and Commitments

We lease office, laboratory and storage space in facilities at several locations in California and Massachusetts. The terms of our lease agreements have expiration dates between 2023 to 2033. The total future minimum lease payments under the agreements are $110.8 million, of which $7.6 million of the payments are due in 2022. See Note 6 to our condensed consolidated financial statements.

We are party to license agreements pursuant to which we have in-licensed various intellectual property rights. The license agreements obligate us to make certain milestone payments related to achievement of specified events, as well as royalties in the low-single digits based on sales of licensed products. During the three months ended March 31, 2022 and 2021, no royalties were due from the sales of licensed products. The table above does not include any milestone or royalty payments to the counterparties to these agreements as the amounts, timing and likelihood of such payments are not known. See Note 8 to our condensed consolidated financial statements for additional information.

In September 2017, we entered into a contract research and development agreement with a third party CRO to provide research, analysis and antibody samples to further the development of our antibody drag candidates. During the three months ended March 31, 2022, we had no research and development expense under the agreement. During the three months ended March 31, 2021, we had immaterial research and development expense under the agreement.

We are also obligated to pay the CRO certain milestone payments of up to $36.4 million on achievement of specified events. None of these events had occurred as of March 31, 2022. However, we are unable to estimate the timing or likelihood of achieving the milestones and, therefore, any related payments are not included in the table above.

In May 2019, we entered into a contract research and testing agreement with another third-party CRO to provide antibody discovery related services. In March 2022, we notified such CRO of its intent to terminate the agreement effective as of May 17, 2022. Until such date, we are obligated to pay such CRO certain milestone payments of up to $34.8 million on achievement of specified events. None of these events had occurred as of March 31, 2022. No research and development expense was recorded under the agreement during the three months ended March 31, 2022 and 2021.

From time to time, in the normal course of business, we enter into contracts with CROs for clinical trials, CMOs for clinical supply manufacturing and with vendors for preclinical research studies and other services and products for operating purposes, which generally provide for termination within 30 days of notice. Therefore, all such contracts are cancelable contracts and not included in the table above.

Critical Accounting Policies and Use of Estimates

This discussion and analysis of financial condition and results of operation is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities as of the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to preclinical study trial accruals, fair value of assets and liabilities, and the fair value of common stock and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

There have been no changes to our critical accounting policies since we filed our Annual Report on Form 10-K for the year ended December 31, 2021 with the SEC on March 10, 2022. For a description of our critical accounting policies, please refer to our Annual Report on Form 10-K we filed with the SEC on March 10, 2022.

Recent Accounting Pronouncements

Refer to “Note 2. Summary of Significant Accounting Policies” in the notes to our unaudited interim condensed consolidated financial statements in Part I, Item 1 of this report, for a discussion of recent accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

There have been no material changes in market risk from the information provided in “Item 7A. Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the year ended December 31, 2021.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of March 31, 2022, management, with the participation of our principal executive, financial and accounting officers, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms,

and that such information is accumulated and communicated to our management, including the principal executive, financial and accounting officers, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2022, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(e) and 15d-15(e) of the Exchange Act that occurred during the three months ended March 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, 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 report, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Many of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Summary of Principal Risks Associated with Our Business

- We are a biotechnology company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability;
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control, including the ongoing COVID-19 pandemic and related clinical trial enrollment challenges;
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations
- Our immunotherapy approach is based on novel ideas and technologies that are unproven and may not result in marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval;
- Our business remains highly dependent on the successful development, regulatory approval and commercialization of our individualized immunotherapy product candidate, GRANITE, our "off-the-shelf" immunotherapy product candidate, SLATE, and CORAL, our second generation COVID-19 vaccine, all of which are in clinical trials;
- We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations;
- The COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease, may materially adversely affect our business and operations;

- We rely on third parties in the conduct of all of our preclinical studies and intend to rely on third parties in the conduct of all of our future clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements, or fail to meet expected deadlines, we may be unable to obtain regulatory approval for our immunotherapy product candidates;

- We currently perform the majority of the manufacturing of our product candidates internally and rely on qualified third parties to supply some components of our product candidates. Our inability to manufacture sufficient quantities of GRANITE, SLATE, CORAL or any future product candidates, or the loss of our third-party suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially adversely affect our business;

- We face significant competition in an environment of rapid technological and scientific change, and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do, and we may not be able to successfully compete;

- Our success depends on our ability to protect our intellectual property and our proprietary technologies and to avoid infringing the rights of others; and

- Our stock price is volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

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

We are a biotechnology company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability.

Product development in the biotechnology industry is a highly speculative undertaking and involves a substantial degree of risk. We have a limited operating history upon which you can evaluate our business and prospects. We have no products approved for commercial sale and have not yet generated any revenue from product sales. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry.

We have incurred significant operating losses in each year since our inception in August 2015 (for additional information, see “Liquidity” in Note 1 to our condensed consolidated financial statements). Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Our clinical programs will require substantial additional development time and resources before we (or our collaboration partners) would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. In addition, we incur substantial costs associated with operating as a public company. We also do not yet have a sales organization or commercial infrastructure and, accordingly, if our product candidates are approved, we will incur significant expenses to develop a sales organization or commercial infrastructure in advance of generating any commercial product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our current and any future immunotherapy product candidates, conduct clinical trials and pursue research and development activities. Even if we achieve profitability at some point in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders’ equity and our working capital.

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

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for tumor-specific cancer immunotherapies and infectious disease programs, in addition to establishing our in-house manufacturing capabilities. Preclinical studies, clinical trials and additional research and development activities will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the development of our current and any future product candidates we may choose to pursue, as well as the continued development of our manufacturing capabilities and other corporate uses. Specifically, in the near term, we expect to incur substantial expenses as we advance our GRANITE, SLATE and CORAL programs through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization, continue our research and development efforts and invest in our manufacturing facility. These expenditures will include, among others, costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals, and manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of GRANITE, SLATE, CORAL or any of our future product candidates.

We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operations for at least twelve (12) months. However, our operating plans and other demands on our capital resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity, debt financings or other sources, such as strategic collaborations. In addition, 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. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of developing each of our product candidates, including conducting preclinical studies and clinical trials, either on our own or in collaboration with others;
- potential delays in our ongoing clinical trials as a result of the COVID-19 pandemic;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing and amount of any milestone, royalty or other payments we are required to make pursuant to any current or future collaboration or license agreement;
- the cost of manufacturing our tumor-specific immunotherapies we successfully commercialize, including the cost of scaling up our internal manufacturing operations;
- the cost of building a sales force in anticipation of product commercialization;
- the cost of commercialization activities, including legal, compliance, marketing, sales and distribution costs;

- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;

- any product liability or other lawsuits related to our products;

- the expenses needed to attract, hire and retain skilled personnel;

- the costs associated with being a public company;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and

- the timing, receipt and amount of sales of any future approved products, if any.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate our preclinical studies, clinical trials or other research and development activities or eliminate one or more of our development programs altogether; or

- delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish valuable rights to our product candidates, grant licenses on terms that may not be favorable to us or jointly own some aspects of our technologies or product candidates that we would otherwise pursue on our own. We may not realize revenue from sales of products or royalties from licensed products in the foreseeable future, and no such revenue will be realized unless and until a product candidate is clinically tested, approved for commercialization and successfully marketed. To date, we have primarily financed our operations through the sale of equity securities. We will be required to seek additional funding in the future and currently intend to do so through collaborations, public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of such funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available to us on acceptable terms or at all. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants, repayment obligations, or other similar restrictions that may affect our business and limit our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities receive any distribution of our assets.

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

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

- the timing and cost of, and level of investment in, research, development and commercialization activities, which may change from time to time;
- the timing of receipt of approvals from regulatory authorities in the United States and internationally;
- the timing and status of enrollment for our clinical trials;
- the cost of manufacturing, as well as building out our supply chain, which may vary depending on the quantity of production, the cost of continuing to establish and scale up our internal manufacturing capabilities, and the terms of any agreements we enter into with third-party suppliers;
- timing and amount of any milestone, royalty or other payments due under any current or future collaboration or license agreement;
- coverage and reimbursement policies with respect to our immunotherapy product candidates, if approved, and potential future drugs that compete with our products;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- the level of demand for our immunotherapy products, if approved, which may vary significantly over time;
- the extent to which the COVID-19 pandemic, as it continues to evolve, may impact our operations;
- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our 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. Such a stock price decline could occur even when we met any previously publicly stated revenue or earnings guidance we may provide.

Risks Related to Our Business

Our business is highly dependent on the successful development, regulatory approval and commercialization of our product candidates, primarily our individualized immunotherapy product candidate, GRANITE, our "off-the-shelf" immunotherapy product candidate, SLATE, and CORAL, our second generation COVID-19 vaccine candidate, all of which are in clinical trials.

We have no products approved for sale, and all three of our clinical programs are in Phase 1 or Phase 2 clinical trials. As such, we face significant clinical risk with our programs and our tumor and viral-specific immunotherapy approach generally. The success of our business, including our ability to finance our operations and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of GRANITE, SLATE and CORAL, as well as other product candidates, which may never occur. In the future, we may also become dependent on other product candidates that we may develop or acquire. Our product candidates have, to date, only been tested in a small number of humans, and, given our clinical stage of development, it may be many years, if at all, before we will have demonstrated the safety and efficacy, especially of an individualized immunotherapy treatment sufficient to warrant approval for commercialization.

We have not previously submitted a BLA to the FDA, or similar filing seeking regulatory approval to comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market a product candidate, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

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

The clinical and commercial success of our current and any future product candidates will depend on several factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower, or cost more, than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- our ability to timely execute our ongoing clinical trials and enroll a sufficient number of patients on a timely basis to evaluate the potential of our product candidates in clinical development;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support approval of our product candidates;
- our ability to complete an IND, or similar foreign applications, enabling studies, and successfully submit an IND or similar foreign applications for future product candidates;

- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;

- our ability to consistently manufacture on a timely basis our product candidates;

- our ability, and the ability of any third parties with whom we contract, to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMPs or similar foreign requirements;

- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy, quality and acceptable risk-benefit profile of our product candidates;

- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;

- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;

- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our current or any future product candidates or approved products, if any;

- the willingness of physicians, operators of hospitals and clinics and patients to utilize or adopt our individualized cancer immunotherapy approach;

- our ability to successfully develop a commercial strategy and thereafter commercialize GRANITE, SLATE, CORAL or any future product candidates (including our partnered HIV therapeutic vaccine) in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;

- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid) and other third-party payors for any of our product candidates that may be approved;

- the convenience of our treatment or dosing regimen;

- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;

- patient demand for our current or future product candidates, if approved;

- our ability to establish and enforce intellectual property rights in and to our product candidates; and

- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates. Even if regulatory

approvals are obtained, we may never be able to successfully commercialize any product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business or achieve profitability.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. We may experience delays in enrolling or completing our clinical trials. Additionally, we cannot be certain that studies or trials for our product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- delays in obtaining regulatory authorization to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining Institutional Review Board, or IRB/Ethics Committees, and, where required, Institutional Biosafety Committee (IBC) approval at each trial site;
- recruiting an adequate number of suitable patients to participate in a trial, particularly in light of the unpredictable impact of the COVID-19 pandemic on patient enrollment and clinical site closures;
- having subjects complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing subject safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites;
- obtaining sufficient quantities of product candidates for use in preclinical studies or clinical trials from third-party suppliers; or
- accessing checkpoint inhibitors for use in combination with our product candidates in preclinical studies or clinical trials, including checkpoint inhibitors that have not been approved by the FDA for such use.

Despite encouraging signs of improvement in the COVID-19 pandemic, the emergence of new variants and/or waning of vaccine efficacy may increase the likelihood that we encounter challenges and delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We are also aware that several CROs based in the U.S. that provide preclinical services are experiencing heavy demand, which may impact their ability to start new

studies and lead to delays in the commencement of our preclinical studies. In addition, several U.S.-based academic research organizations have also experienced shutdowns during the initial phase of the COVID-19 pandemic, and this may recur if there is a resurgence of, or emergence of new, SARS-CoV-2 variants. However, to date neither of these has caused any material impact on our business.

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

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- we may be affected by safety concerns that have a class effect; for example, if a competitor reports negative results with respect to a compound similar to those we are developing, such setbacks could negatively impact our own product development;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our development programs, including our individualized cancer immunotherapy program;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we or our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, or be unable to produce sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive, or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements, which could be expensive and time consuming; or
- have the treatment removed from the market after obtaining marketing approval.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the competent Ethics Committees/IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board (DSMB), for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for certain of our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, we fail to ensure such relationships and compensation are adequately disclosed, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates.

If any of our preclinical studies or clinical trials of our product candidates are delayed or terminated, the commercial prospects of our product candidates may be harmed, and our ability to generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business,

financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If our product candidates or our immunotherapy prediction platform generally prove to be ineffective, unsafe or commercially unviable, our entire platform and approach would have little, if any, value, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union recently evolved. The Clinical Trial Regulation (CTR), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate Clinical Trial Agreement (CTA) to be submitted in each member state to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs may impact our developments plans.

It is currently unclear to what extent the United Kingdom, as a free-standing regulatory regime outside of the European Union, will seek to align its regulations with the European Union. The UK regulatory framework in relation to clinical trials is derived from the EU Clinical Trials Directive (as implemented into UK law, through secondary legislation). On January 17, 2022, the Medicines and Healthcare Products Regulatory Agency (MHRA) launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 (although a response has not yet been published) and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the United Kingdom chooses to align with the EU regulation or diverge from it to maintain regulatory flexibility. A decision by the United Kingdom not to closely align its regulations with the new approach that will be adopted in the European Union may have an effect on the cost of conducting clinical trials in the United Kingdom as opposed to other countries and/or make it harder to seek a marketing authorization in the European Union for our product candidates on the basis of clinical trials conducted in the United Kingdom.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may also be impacted.

Our tumor-specific cancer immunotherapy approach is based on novel ideas and technologies that are unproven and may not result in marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.

Regarding our tumor-specific cancer immunotherapies, our foundational science and product development approach are based on our ability to predict the presence of a patient's TSNA and develop a TSNA-directed therapy that will elicit a meaningful T cell response. We believe that this approach may offer an improved therapeutic effect by driving an intense, focused T cell attack selectively upon a patient's tumor. However, this approach to treating cancer is novel and the scientific research that forms the basis of our efforts to predict the presence of TSNA and to develop TSNA-directed cancer immunotherapy candidates is both preliminary and limited. The results of our preclinical animal studies may not translate into humans. For example, our prediction model may fail to accurately predict the presence of TSNA, resulting in little or no tumor-targeted T cell response, or our therapy may fail to elicit a significant or durable enough T cell response to effectively destroy a tumor. As such, we cannot assure you, even if

we are able to develop individualized cancer immunotherapy candidates capable of recognizing TSNA and eliciting a T cell response, that such therapy would safely and effectively treat cancers. We may spend substantial funds attempting to develop this approach and never succeed in developing a marketable therapeutic.

No regulatory authority has granted approval for a cancer immunotherapy based on a heterologous prime-boost approach, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications, lines of therapy or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If our personalized immunotherapy candidates prove to be ineffective, unsafe or commercially unviable, our entire technology platform and pipeline would have little, if any, value, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

The regulatory approval process and clinical trial requirements for novel product candidates can be more expensive and take longer than for other, better known or more extensively studied product candidates, and we cannot predict how long it will take or how much it will cost to complete clinical developments and obtain regulatory approvals for a cell therapy product candidate in the United States or how long it will take to commercialize a product candidate, if and when approved. Regulatory requirements governing cell therapy products have changed frequently and may continue to change in the future. For example, the FDA established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, (CBER), to consolidate the review of cell therapies and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. These and other regulatory review agencies, committees and advisory groups and the requirements and guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval limitations or restrictions. Additionally, under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies. Additionally, adverse developments in clinical trials conducted by others of cell therapy products or products created using similar technology, or adverse public perception of the field of cell therapies editing, may cause the FDA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing technologies such as ours, either of which could materially harm our business. As we advance our product candidates, we will be required to consult with various regulatory authorities, and we must comply with applicable laws, rules and regulations, which may change from time to time, including during the course of development of our product candidates. If we fail to do so, we may be required to delay or discontinue the clinical development of certain of our product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Even if we comply with applicable laws, rules, and regulations, and even if we maintain close coordination with the applicable regulatory authorities with oversight over our product candidates, our development programs may fail to succeed. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market would materially adversely affect our business, financial condition, results of operations and prospects.

Results of earlier studies and trials of our product candidates may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical trial process. Success in preclinical studies and early clinical

trials does not ensure that later clinical trials will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. In addition, the results of our preclinical animal studies, including our non-human primate studies, may not be predictive of the results of outcomes in human clinical trials. For example, our tumor-specific cancer immunotherapy candidates and any future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Even if we are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates.

The design of our clinical trials may provide encouraging albeit limited evidence of the efficacy of our individualized immunotherapy product candidate, GRANITE and the off-the-shelf immunotherapy candidate, SLATE, respectively.

Scientific principles and preclinical data suggest that combination treatment of cancer patients with our TSNA-directed immunotherapy product candidates plus checkpoint inhibitors is likely to be most effective for our target indications. The Phase 1 portion of both of our Phase 1/2 clinical trials, GO-004 (NCT03639714) and GO-005 (NCT03953235), consequently, involved administration of a combination therapy with GRANITE and SLATE, respectively. Notably, all patients in the Phase 1/2 trials received anti-PD-1 monoclonal antibodies (mAb) as background therapy. Some patients in both Phase 1 portions of our trials additionally received anti-CTLA-4 mAb. Checkpoint inhibitors such as anti-PD-1 and anti-CTLA-4 mAb are known to be effective treatments in many cancer patients and elicit objective responses in some patients. Any objective responses observed in our trials thus would have been in patients receiving our experimental therapy together with at least one checkpoint inhibitor, and attribution of objective responses to the effects of GRANITE or SLATE alone are not possible at this stage of our development program. Efficacy will be studied carefully in the respective GRANITE and SLATE Phase 2 cohorts, in which we will attempt to compare the relative contributions of our individualized and off-the-shelf immunotherapy candidates and the checkpoint inhibitors to historical data from patients treated with checkpoint inhibitors alone. Of note, patient eligibility for our clinical trials is determined based, in part, upon predicted immunogenicity of the patient's tumor. In particular, we only accept patients predicted to have a neoantigenic burden above a certain threshold. Selection of high-immunogenicity tumors is relevant to interpretation of clinical data, since high immunogenicity (which is related to high tumor mutational burden) may be a positive prognostic factor, which means our selected patients would have a clinical outcome upon standard therapy that is superior to unselected case controls. Conversely, we are also enriching our GRANITE Phase 2 cohorts with patients with intermediate mutational burden, such as MSS-CRC, who do not respond or poorly respond to checkpoint inhibitors. While clinical response in these patients when receiving our individualized vaccines in combination with checkpoint inhibitors would be encouraging, the absence of a randomized controlled cohort will make the interpretation of these results difficult. Overall, interpretation of "time-to-event" endpoints, such as progression-free survival or overall survival, is challenging without a contemporaneous, randomized control group. As a result, even if our respective Phase 1/2 clinical trials provide early, encouraging results, they may yield limited evidence of the efficacy of GRANITE or SLATE, which may not be fully understood by investors or market participants, potentially leading to negative effects on our stock price.

Our tumor-specific and infectious disease product candidates are biologics with complex and time-consuming manufacturing processes, and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Our immunotherapy product candidates, GRANITE, SLATE and CORAL, are considered to be biologics, and their manufacturing processes are complex, time-consuming, highly-regulated and subject to multiple risks. Our product candidates for SLATE and CORAL are designed using known genetic sequences available from public

databases, while the manufacture of our product candidate GRANITE involves extraction of genetic material from patient tumor samples. GRANITE, SLATE and CORAL require genetic manipulations at the gene sequence level, live cell culture operations, specialized formulations and aseptic fill finish operations. As a result of such complexities, the cost to manufacture biologics in general, and our individualized immunotherapy GRANITE in particular, is generally higher than traditional small molecule chemical compounds. The manufacturing process is also less reliable and more difficult and time-consuming to reproduce. For example, the entire cGMP manufacturing process, from biopsy receipt and sequencing completion to the release and shipment of GRANITE to the clinical site for patient administration, currently takes approximately 14-18 weeks. In addition, our manufacturing processes for GRANITE, SLATE and CORAL are in their clinical stages of development and will be susceptible to product loss or failure, or product variation that may adversely impact patient outcomes. Our supply chain may not function efficiently due to logistical issues associated with, but not limited to, the collection of a tumor biopsy from the patient, shipping such material to the manufacturing site, sequencing the biopsy specimen, manufacturing the immunotherapy components, shipping the final immunotherapy back to the patient, and injecting the patient with the immunotherapy. Manufacturing issues or different product characteristics resulting from process development activities or even minor deviations during normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If for any reason we lose a patient's biopsy or an in-process product at any point in the process, the manufacturing process for that patient will need to be restarted, and the resulting delay may adversely affect that patient's outcome. Because GRANITE is manufactured specifically for an individual patient, we will be required to maintain a chain of identity and chain of custody with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity and chain of custody is difficult and complex, and the failure to do so could result in adverse patient outcomes, loss of product or regulatory action, including withdrawal of our products from the market, if licensed.

As part of our process development efforts for GRANITE, SLATE and CORAL, we also may make changes to our manufacturing processes at various points during development. Such changes are made for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Any changes carry the risk that they will not achieve their intended objectives, could cause our product candidates to perform differently and affect the results of our ongoing or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the clinical development phase may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

Furthermore, if microbial, viral or other contaminations are discovered in our supply of our product candidates or in our manufacturing facilities, or those of our CMOs, such manufacturing facilities may need to be closed for extended periods of time to investigate and remedy the contamination. We cannot assure you that any such contaminations or stability failures or other issues relating to the manufacturing of our product candidates will not occur in the future.

We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay or prevent commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

To gain approval to market our product candidates, we must provide the FDA and foreign regulatory authorities with clinical data that adequately demonstrate the safety, purity, potency and efficacy of the product candidate for the intended indication applied for in the applicable regulatory filing. Product development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical development programs. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct.

We have not previously submitted a BLA or any other marketing application to the FDA or similar filings to comparable foreign regulatory authorities. A BLA or other similar regulatory filing requesting approval to market a

product candidate must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, effective, pure and potent for each desired indication. The BLA or other similar regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. FDA and foreign regulatory authorities may also conduct pre-license inspections of us and/or our CMOs to ensure the manufacture of a product candidate complies with applicable regulatory requirements, including cGMP or similar foreign requirements. Adverse inspection findings could result in the delay or non-approval of a BLA or other similar regulatory filing and require the implementation of costly corrective actions before potential approval can be granted.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that any of our product candidates are safe, pure, potent and effective for the requested indication;

- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocols or the interpretation or reliability of data from preclinical studies or clinical trials;

- our inability to demonstrate that the clinical and other benefits of any of our product candidates outweigh any safety or other perceived risks;

- the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical trials;

- the FDA's or the applicable foreign regulatory agency's non-approval of the formulation, labeling or specifications of GRANITE, SLATE, CORAL or any of our future product candidates;

- the FDA's or the applicable foreign regulatory agency's failure to approve our manufacturing processes and facilities or the facilities of third-party manufacturers upon which we rely; or

- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval. For example, the FDA launched Project Optimus as an initiative to reform the dose optimization and dose selection paradigm in oncology product development as the FDA's view is that the current paradigm for dose selection results in doses and schedules of molecularly targeted therapies that are inadequately characterized before initiating registration/pivotal trials. Through collaboration with industry, academia, and other stakeholders, the FDA's goal for this initiative is to advance an oncology dose-finding and dose optimization paradigm that emphasizes dose selections that maximize efficacy as well as safety and tolerability. In support of this initiative, the FDA may request sponsors of oncology product candidates to conduct dose optimization studies pre- or post-approval. FDA also continues to develop and finalize guidance documents and implement initiatives regarding the development and clinical research of oncology product candidates.

Additionally, in part due to questions raised by the process underlying the approval of the Alzheimer's disease drug Aduhelm®, government authorities and other stakeholders have been recently scrutinizing the accelerated approval pathway, with some stakeholders advocating for reforms. Even prior to the Aduhelm approval, the FDA has held Oncologic Drugs Advisory Committee meetings to discuss accelerated approvals for which confirmatory trials

have not verified clinical benefit. Such scrutiny, among other factors, has resulted in voluntary withdrawals of certain products and indications approved on an accelerated basis. The FDA also launched an initiative, known as Project Confirm, to promote the transparency of outcomes related to accelerated approvals for oncology indications. Moreover, spurred by the Aduhelm controversy, the U.S. Department of Health and Human Services Office of Inspector General has initiated an assessment of how the FDA implements the accelerated approval pathway. In addition, Members of Congress have introduced proposed legislation to revise the statutory accelerated approval pathway, including with respect to FDA's ability to rapidly withdraw products and indications for which effectiveness is not confirmed in post-market studies. At this time, it is not clear what, if any, impact these developments may have on the statutory accelerated approval pathway or our business, financial condition, results of operations or prospects.

Of the large number of biopharmaceutical products in development, only a small percentage successfully complete the FDA or other regulatory bodies' approval processes and are commercialized.

Even if we eventually complete clinical testing and receive approval from the FDA or applicable foreign agencies for any of our product candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials which may be required after approval. Failure to complete such post-marketing requirements in accordance with the timelines and conditions set forth by the FDA or the applicable foreign regulatory agency could significantly increase costs or delay, limit or ultimately restrict the commercialization of the product candidate. The FDA or the applicable foreign regulatory agency also may approve one or more of our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory agency, may not approve our product candidates with the labeling that we believe is necessary or desirable for the successful commercialization of such product candidates.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially adversely impact our business and prospects.

We have chosen to prioritize development of our individualized immunotherapy candidate, GRANITE, our off-the-shelf immunotherapy candidate, SLATE, and our second-generation COVID-19 vaccine program, CORAL. We may expend our limited resources on candidates or indications that do not yield a successful product and fail to capitalize on other product candidates or indications for which there may be a greater likelihood of success or that may be more profitable.

We initially developed our GRANITE individualized cancer immunotherapy candidates based on the prediction of a patient's TSNA, to address a variety of cancers, including NSCLC and gastro-esophageal, bladder and colorectal cancers. GRANITE is now being evaluated in the Phase 2 portion of the GO-004 trial (NCT03639714), which started enrolling patients in the third quarter of 2020 with an objective to identify interpretable signals of efficacy when combining our vaccine candidate with immune checkpoint inhibitors with a focus on tumor types that do not respond to immune checkpoint inhibitors (MSS-CRC), respond poorly (gastro-esophageal cancers) or have progressed after first-line therapy with immune checkpoint inhibitors (NSCLC). The clinical trial of SLATE, our off-the-shelf product candidate, is currently evaluating subjects with mutation positive and metastatic and advanced solid tumors, with a focus on NSCLC, who seem to derive the strongest benefit in terms of immune response as compared to patients with colorectal and pancreatic cancers. SLATE is now being evaluated in the Phase 2 portion of the GO-005 trial (NCT03953235), which is now focusing on patients with NSCLC and MSS-CRC. Based on findings in the earlier portion of the SLATE study, we have developed an improved KRAS-focused cassette to treat patients with KRAS-positive tumors, which entered the clinic in the third quarter of 2021. We may resume accrual of patients with pancreatic cancer once this updated version of the SLATE product candidate has shown benefits in terms of immunological and/or clinical response in patients with NSCLC or MSS-CRC. We have strategically determined to initially focus solely on the development of individualized cancer immunotherapy candidates (including our "off-the-shelf" immunotherapy candidate) rather than pursue other types of immunotherapies based, in part, on the significant resources required to develop and manufacture immunotherapies. As a result, we may initially be foregoing other potentially more profitable therapy indications or those with a greater likelihood of success.

We initiated the CORAL program in 2021, and since have advanced five clinical stage potential product candidates being studied across a variety of populations across four clinical studies and established partnerships and funding agreements to help support the trials. We are committed to seeing the current studies through completion and if successful and regulatory circumstances allow, would seek to execute a pivotal trial. If we are unable to obtain

regulatory approval and/or funding for a pivotal trial within our CORAL program, our commercial opportunity and profitability may be limited. We are assessing options to fund a pivotal trial should it occur.

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal 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 oncology or biopharmaceutical industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.

If we are unable to obtain regulatory approval for use of our tumor-specific immunotherapy candidates, GRANITE and SLATE, as a first- and second-line therapy, our commercial opportunity and profitability may be limited.

Cancer therapies for advanced/metastatic cancers are sometimes characterized as first-line, second-line or third-line, and the FDA often approves new systemic therapies initially only for third-line use. When cancer is detected early enough, surgery plus first-line systemic therapy is sometimes adequate to cure the cancer. Whenever first-line therapy (usually chemotherapy, hormone therapy, radiotherapy, surgery or a combination of these) proves unsuccessful, second-line therapy may be administered. Second-line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules or a combination of these. Third-line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies and new technologies such as adoptive cell therapies.

Traditionally, novel oncology therapeutics are developed and approved in late (third) line therapy of cancer patients. Such clinical programs carry risk of failure because patients are often quite frail, with effects of multiple rounds of prior therapy weakening bone marrow, immune systems and general fitness. Immunotherapy, such as checkpoint inhibitors, has generally been shown to be more effective when used in earlier lines of therapy, with the prospect of very durable responses in some patients; and there is a trend towards earlier use of these agents, avoiding in particular cytotoxic chemotherapy agents, which carry substantial toxicity and very little prospect of long-term responses. Our tumor-specific immunotherapy clinical development program also aims to study our products in early stages of cancer treatment (referred to as adjuvant therapy), which carry a higher safety bar, and often a greater expectation of efficacy over control arms. Such studies may thus be relatively large and slow to achieve maturity. There are new tools available to stratify cancer patients for risk of recurrence or progression, such as liquid biopsies that measure the amount of circulating tumor-derived DNA. We will utilize these tools to attempt to expedite clinical trials in early-stage cancer patients by focusing upon patients at above-average risk of disease recurrence or progression, which events are typical endpoints in clinical trials. The development of liquid biopsies is at an early stage, however, and these tools may prove to carry low utility and thus render early-stage cancer trials slow, necessarily large and expensive. The safety of our tumor-specific immunotherapy product candidates in combination with checkpoint inhibitors in early lines of therapy may also prove to be unacceptable.

We expect to seek approval of our tumor-specific immunotherapy product candidates as late-line therapy where appropriate, but also as a first-line therapy wherever possible, and potentially as adjuvant therapy. There is no guarantee that our product candidates, even if approved in late-line therapy, would be approved for second-line or first-line or adjuvant therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for first-line or adjuvant therapy.

While our SLATE product is designed to be readily available (off-the-shelf), GRANITE currently takes approximately 14-18 weeks post-sequencing to be manufactured and released for human use. Such long timeline demands that either patients are consented and entered into our trials when they start a prior line of therapy, and start our therapy upon disease progression, or we initiate treatment in patients who have entered the maintenance phase of

their original line of treatment. For example, we might enroll newly diagnosed patients who are due to receive front-line chemotherapy and then start their therapy with our immunotherapy product candidate as second-line treatment when they progress upon front-line chemotherapy or fail to tolerate it. This carries the risk of time delays or drop-out, i.e., patients may not progress after first-line chemotherapy for a long time or they may decide not to receive an immunotherapy product candidate we have manufactured for them, at our expense. Alternatively, we may treat first-line patients once they have completed their initial treatment and have not progressed (called maintenance therapy). This renders efficacy harder to interpret versus simple treatment studies (any objective response cannot clearly be attributed to our products) and may be complicated by standard of care treatments, which may necessarily be continued alongside our immunotherapy candidates, further confounding interpretation of efficacy.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive first-, second- or third-line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, and market research, and may prove to be incorrect. Regulatory authorities also may establish narrower definitions around when a patient is ineligible for other treatments than we have used in our projections, and that would reduce the size of the patient population eligible for our product candidates. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, we anticipate that only a fraction of colorectal cancer patients will be predicted to have a high enough probability of TSNA presence to merit their inclusion into our program. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first-line or second-line therapy.

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

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

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinical trial investigators' willingness to continue enrolling patients during the COVID-19 pandemic;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new therapies that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient consents.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. While the COVID-19 pandemic appears to be receding in the United States, there is an unquantifiable risk of emergence of variants or current vaccine escape that could impact and delay patient enrollment and generate challenges in monitoring patients once on study. We anticipate facing additional challenges if the COVID-19 pandemic worsens.

Further, the targeting of TSNA may result in unforeseen events, including harming healthy tissues in humans. As a result, it is possible that safety concerns could negatively affect patient enrollment among the patient populations that we intend to treat. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

As with most biological products, use of our product candidates could be associated with side effects or adverse events, which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. While we have now completed the Phase 1 portions, and we are in the Phase 2 portions, of our clinical trials of GRANITE and SLATE, we do not yet have a comprehensive understanding of their risks, and it is likely that there will be side effects associated with their use in increasing numbers of patients in Phase 2 and beyond. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. Our other product candidates present similar risks, the severity of which is difficult to predict.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, or comparable foreign regulatory authorities, the IRBs at the institutions in which our studies are conducted, the competent Ethics Committees or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, even if we successfully advance one of our product candidates through clinical trials, such trials will likely only include a limited number of subjects and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period.

There have been several reported cases of severe thrombosis with thrombocytopenia occurring post-vaccination in individuals who received adenovirus-based vaccines for SARS-CoV-2, including those administered under emergency use authorization. This syndrome has been termed “vaccine-induced prothrombotic immune thrombocytopenia (VIPIT)” or “vaccine-induced immune thrombotic thrombocytopenia (VITT)” but is now termed “thrombosis with thrombocytopenia syndrome (TTS)” by the Centers for Disease Control and Prevention (CDC) and the FDA. The syndrome appears to be autoimmune in nature and is associated with autoantibodies to a specific platelet-associated antigen. To date, no patients receiving our adenoviral vaccine candidate against SARS-CoV-2, CORAL, have been known to develop TTS, nor have we observed it in our cancer programs where our adenoviral

vaccines are used in conjunction with checkpoint inhibitors (e.g., anti-PD1 antibody), which themselves can be associated with autoimmune toxicities; but we cannot be certain that this or similar complications will not arise.

If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may vary, suspend or withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS), or similar risk management measures, or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially adversely affect our results of operations and business. In addition, if one or more of our product candidates or our TSNA-directed immunotherapy approach generally prove to be unsafe, our entire technology platform and pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if one of our product candidates obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

Even if one of our product candidates receives FDA or other regulatory approvals, the commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. The degree and rate of physician and patient adoption of our current or future product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the safety and efficacy of our product as compared to other available therapies;
- the time required for manufacture and release of our individualized immunotherapy products;

- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid) and other third-party payors for any of our product candidates that may be approved;
- acceptance by physicians, operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies for a particular indication;
- proper training and administration of our product candidates by physicians and medical staff;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience, including, for example, the convenience of any dosing regimen;
- the cost of treatment with our product candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved, on the part of insurance companies and other third-party payers, physicians and patients;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA or foreign regulatory authorities - approved labeling for our products;
- the willingness of physicians, operators of hospitals and clinics and patients to utilize or adopt our products as a solution;
- any FDA or foreign regulatory authorities' requirement for a REMS or similar risk management measures;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our products or favorable publicity about competitive products; and
- potential product liability claims.

We cannot assure you that our current or future product candidates, if approved, will achieve broad market acceptance among physicians and patients. Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our results of operations.

We currently perform the majority of the manufacturing of our product candidates internally and rely on qualified third parties to supply some components of our product candidates. Our inability to manufacture sufficient quantities of GRANITE, SLATE, CORAL or any future product candidates, or the loss of our third-party suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially adversely affect our business.

Manufacturing is a vital component of our immunotherapy approach, and we have invested significantly in our manufacturing facility. To ensure timely and consistent product supply assurance to our patients we previously used a hybrid product supply approach whereby certain elements of our product candidates were manufactured internally at our manufacturing facilities in Pleasanton, California, and other elements were manufactured at qualified

third-party CMOs. All internal and third-party contract manufacturing is performed under cGMP or similar guidelines. We have internalized a majority of the manufacturing steps to optimize cost and production time, as well as establish full control over intellectual property and product quality. We will need to continue to scale up our manufacturing operations, as we continue to build the infrastructure and improve the capability internally to manufacture all supplies needed for our product candidates or the materials necessary to produce them for use in the conduct of our preclinical studies or clinical trials. We currently lack the internal resources and the capability to manufacture certain elements of our product candidates on a clinical scale. Accordingly, we have made, and will be required to continue to make, significant investments in our manufacturing facility and processing in the future, and our efforts to scale our manufacturing operations may not succeed.

Our facilities and the facilities used by our CMOs to manufacture our product candidates are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. We do not control the manufacturing process at our CMOs and are completely dependent on them for compliance with current regulatory requirements. If we or our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on our or their manufacturing facilities for the manufacture of elements of our product candidates. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds our facilities or those of our CMOs inadequate for the manufacture of our product candidates, or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates.

Additionally, even if one of our vaccine candidates receives regulatory approval, successful commercialization depends on our ability to effectively scale up our in-house manufacturing capabilities and those of our manufacturing partners and contractors. Although we have a dedicated manufacturing facility in Pleasanton, we do not have sufficient manufacturing infrastructure to support a global roll-out of our product candidates on our own. We may not be able to timely and effectively produce our vaccine candidates, if approved, in adequate quantities to address global demand. We have not previously had a commercial launch of any vaccine product and doing so in a pandemic environment with an urgent, critical global need creates additional challenges. We cannot guarantee that any of these new challenges and requirements will be met in a timely manner or at all.

Finally, we and our CMOs may experience manufacturing and raw material sourcing difficulties due to resource constraints, as a result of labor disputes or unstable political environments, or due to the impact of the COVID-19 pandemic. If we or our CMOs were to encounter any of these difficulties, our ability to provide our product candidates to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized.

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

We rely on third-party suppliers for certain materials required for the production of our individualized immunotherapy candidate. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of 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 larger competitors. 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, particularly if the COVID-19 pandemic worsens. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

We rely on third parties in the conduct of all of our preclinical studies and intend to rely on third parties in the conduct of all of our future clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or fail to meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.

We currently do not have the ability to independently conduct preclinical studies that comply with Good Laboratory Practice (GLP) regulatory requirements. We also do not currently have the ability to independently conduct any clinical trials. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as Good Clinical Practice (GCP) requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials on our product candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant preclinical studies and our GCP-compliant clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our GLP-compliant preclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. Further, under certain circumstances, these third parties may terminate their agreements with us upon as little as 10 days' prior written notice. Some of these agreements may also be terminated with immediate effect by such third parties under certain other circumstances, including our insolvency. If the third parties conducting our preclinical studies or our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GLPs/GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our financial results and the commercial prospects for our product candidates could be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA or foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, in March, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July, 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plan to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We face significant competition in an environment of rapid technological and scientific change, and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do, and we may not be able to successfully compete.

The biotechnology and pharmaceutical industries in particular are characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. We compete with a variety of multinational biopharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. Our competitors have developed, are developing or will develop product candidates and processes competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that enter the market. We believe that a significant number of product candidates are currently under development, and may become commercially available in the future, for the treatment of diseases and other conditions for which we may try to develop product candidates. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical and antibody and immunoregulatory therapeutics fields. We believe that, while our discovery platform, its associated intellectual property and our scientific and technical know-how give us a competitive advantage in this space, competition from many sources remains. Our competitors include larger and better funded biopharmaceutical, biotechnological and therapeutics companies. Moreover, we also compete with current and future therapeutics developed at universities and other research institutions.

Our success will partially depend on our ability to develop and protect therapeutics that are safer and more effective than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products that are safer, more effective, or less expensive than the therapeutics we develop.

For example, if either GRANITE or SLATE is approved, it will compete with a range of therapeutic treatments that are either in development or currently marketed. Indeed, a variety of oncology drugs and therapeutic biologics are on the market or in clinical development. Such marketed therapies range from immune checkpoint inhibitors such as Bristol-Myers Squibb Company's OPDIVO and YERVOY, Merck & Co., Inc.'s KEYTRUDA and Genentech, Inc.'s TECENTRIQ, and T cell engager immunotherapies such as Amgen, Inc.'s BLINCYTO. The most common therapeutic treatments for common solid tumors are chemotherapeutic compounds, radiation therapy, targeted therapies and now immunotherapies. In addition, numerous compounds are in clinical development for cancer treatment. The clinical development pipeline for cancer includes small molecules, antibodies and immunotherapies from a variety of groups, including in the neoantigen space, the bispecific antibody space and engineered cell therapy and TCR space. Many of these companies are well-capitalized and, in contrast to us, have significant clinical experience.

Additionally, we may be unable to produce a successful second-generation COVID-19 CORAL vaccine candidate, and establish a competitive market share for such CORAL vaccine candidate before the COVID-19 outbreak is contained or significantly diminished. A large number of vaccine manufacturers, academic institutions and other organizations have developed COVID-19 vaccines or are developing COVID-19 vaccine candidates. In particular, Moderna and Pfizer/BioNTech received full approval for their COVID-19 vaccines in the U.S. and other countries, Johnson & Johnson received the emergency use authorizations and many other companies, including Novavax, Sinovac Biotech, AstraZeneca, Sinopharm, and Inovio are in various stages of developing and obtaining marketing authorization for COVID-19 vaccine candidates. Furthermore, COVID-19 vaccines approved prior to our CORAL vaccine may develop broad market acceptance that we are challenged to overcome.

Despite funding provided to us to date, many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. If any competitors are successful in producing more efficacious products or if any competitors are able to manufacture and distribute competitive products with greater efficiency there may be a diversion of potential governmental and other funding away from us and toward such other parties. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

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

The availability of coverage and adequacy of reimbursement by managed care plans, governmental healthcare programs, such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates that receive FDA or foreign regulatory approval. Our ability to achieve acceptable levels of coverage and reimbursement for our products or procedures using our products by third-party payors will have an effect on our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. A decision by a third-party payor not to cover or separately reimburse for our products, or procedures using our products, could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates, or procedures using our product candidates, by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the individual European Union Member States or elsewhere will be available for our product candidates or procedures using our product candidates, or any product that we may develop, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

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

investment. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products, especially novel products like our immunotherapy product candidates. No regulatory authority has granted approval for a tumor-specific cancer immunotherapy based on a vaccine approach, and there is no model for reimbursement of this type of product. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

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

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products, and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

If we are unable to support demand for our existing or future services, including ensuring that we have adequate capacity to meet increased demand, or we are unable to successfully manage the evolution of our EDGE™ platform, our business could suffer.

As the demand for our individualized and off-the-shelf immunotherapy candidates increases with our clinical trial needs, we will need to continue to increase our workflow capacity for sample intake and general process improvements, expand our internal quality assurance program, and apply our EDGE™ platform at a larger scale within expected turnaround times. We will need additional certified laboratory scientists and technicians and other scientific and technical personnel to process higher volumes of tumor biopsies. Portions of our process are not automated and will require additional personnel to scale. We will also need to purchase additional equipment, some of which can take several months or more to procure, set up, and validate, and increase our software and computing capacity to meet increased volume. There is no assurance that any of these increases in scale, expansion of personnel, equipment,

software and computing capacities, or process enhancements will be successfully implemented, or that we will have adequate space in our laboratory facilities to accommodate such required expansion.

As we progress into clinical development and expand our manufacturing capabilities, we will need to incorporate new equipment, implement new technology systems and laboratory processes, and hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher service costs, declining service quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our services and could damage our reputation and the prospects for our business.

We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates effectively in the United States and foreign jurisdictions, if approved, or generate product revenue.

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

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

As of March 31, 2022, we had 201 full-time employees. We will need to continue to expand our managerial, regulatory, clinical science, development operations, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our product candidates or any future product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- manage our preclinical studies and clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees, including sales personnel;
- manage our internal development and operational efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

If we fail to attract and retain senior management and key scientific personnel, our business may be materially adversely affected.

Our success depends in part on our continued ability to attract, retain and motivate highly-qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly our President and Chief Executive Officer, as well as our senior scientists and other members of our senior

management team. The loss of services of any of these individuals could delay or prevent the successful development of our products, initiation or completion of our planned clinical trials or the commercialization of our current or any future product candidates.

Competition for qualified personnel in the biotechnology and biopharmaceutical fields is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

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

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

- decreased demand for our current or future product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize our current or any future product candidates.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our current or any future product candidates we develop. We currently carry product liability insurance covering our clinical trials in the amount of $10.0 million in the aggregate. Nonetheless, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will 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 funds to pay such amounts. Moreover,

in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing any of our product candidates, we intend to expand our insurance coverage to include the sale of such product candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

Our strategic collaborations, including those with Gilead and with 2seventy as well as any future arrangements that we may enter into, may not be successful, which could significantly limit the likelihood of receiving the potential economic benefits of such collaborations and adversely affect our ability to develop and commercialize our product candidates.

In February 2021, we entered into the Gilead Collaboration Agreement with Gilead to research and develop a vaccine for HIV. Under the Gilead Collaboration Agreement, Gilead is responsible for conducting the Phase 1 study and, if it exercises its exclusive option, will develop and commercialize the HIV-specific therapeutic vaccine beyond Phase 1. In such case, and subject to certain clinical, regulatory and commercial milestones being achieved, we would be eligible to receive up to an additional $725.0 million in milestone payments, as well as certain royalties on net sales upon commercialization. Separately, in August 2018, we entered into a strategic collaboration with 2seventy to utilize our EDGE™ platform to identify and validate tumor-specific targets and provide TCRs directed to 10 selected targets for use in 2seventy's cell therapy products. Under the 2seventy Agreement, we are entitled to receive up to an aggregate of $1.2 billion in development, regulatory and commercial milestones and tiered single digit royalties on sales of 2seventy's cell therapy products utilizing the TCRs we develop directed at the targets we discovered.

Apart from these strategic collaborations, in the future we may seek to enter into additional collaboration arrangements for the development or commercialization of certain of our product candidates, depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. To the extent that we decide to enter into collaboration agreements in the future, we may face significant competition in seeking appropriate collaborators. Moreover, all such collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain, as well as challenging to manage. We may not be successful in our efforts with Gilead or 2seventy, and we may never receive any of the payments contemplated in those collaboration arrangements. Further, we may be unable to prudently manage these collaborations or enter into new ones. The terms of any new collaborations or other arrangements that we may establish may not be favorable to us.

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, 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 products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise perform satisfactorily in carrying out these activities;

- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;

- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;

- collaborators may own or co-own intellectual property covering products that result from our collaboration with them, and, in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;

- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; 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 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.

We may evaluate various acquisitions 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 product programs and initiatives in pursuing such a strategic merger or acquisition;

- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and

- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, 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. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

We or the third parties upon whom we depend may be adversely affected by risks beyond our control, such as natural disasters, political crises, acts of terrorism, war or other catastrophic events and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

We, our suppliers and third-party service providers are vulnerable to damage from natural disasters, including but not limited to earthquakes, fires or floods, power loss, communications failures, public health crises, such as pandemics and epidemics, political crises, such as terrorism, war, political instability or other conflict and similar events. If any disaster were to occur, our ability to operate our business at any of our facilities could be seriously, or potentially completely, impaired.

Our corporate headquarters and certain of our other facilities, including our manufacturing facility, are located in the San Francisco Bay Area, which in the past has experienced both severe earthquakes and wildfires. We do not carry earthquake insurance. Earthquakes, wildfires or other natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or other facilities, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. For instance, in late February 2022, Russia invaded Ukraine, and sustained military conflict and disruption in the region is likely. The impact to Ukraine, as well as actions taken by other countries, including new and stricter sanctions by the U.S., Canada, the United Kingdom, the European Union and other countries and organizations against officials, individuals, regions and industries in Russia, Belarus and Ukraine, and each country's potential response to such sanctions, tensions, and military actions could have a material adverse effect on the global economy and political situation. As of the date of this report, we (i) are not conducting clinical or non-clinical studies in either Ukraine, Belarus or Russia, (ii) are not relying upon service providers or vendors from either of these regions to advance our GRANITE, SLATE, or CORAL development programs, (iii) do not source biomanufacturing critical raw materials, equipment, or other supplies directly from either Ukraine, Belarus or Russia, and (iv) are not aware nor have received notification from our supply vendors that the sourcing of any general laboratory or manufacturing materials may be negatively impacted due to such conflict and related sanctions.

The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

We depend on our information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business, including our laboratory information management system and our EDGE™ platform. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to attack and damage from computer viruses, and malware (e.g., ransomware), natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. We have experienced phishing attacks in the past resulting in a security breach of our information technology systems, and we may be a target of phishing attacks or other cyber-attacks in the future. Any significant system failure, accident or security breach could have a material adverse effect on our business, financial condition and results of operations. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to the risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Our business is subject to complex and evolving laws and regulations regarding privacy, data protection and other matters relating to information collection.

There are numerous state, federal and foreign laws, regulations, decisions, and directives regarding privacy and the collection, storage, transmission, use, processing, disclosure and protection of different types of personal data

and personal information and other personal, customer, or other data, the scope of which is continually evolving and subject to differing interpretations. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, the CCPA went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, in November 2020, California voters passed Proposition 24, the CPRA. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In the European Union, the GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. The GDPR has increased our obligations, for example, by imposing higher standards when obtaining consent from individuals to process their personal data, requiring more robust disclosures to individuals, strengthening individual data rights, shortening timelines for data breach notifications, limiting retention periods and secondary use of information, increasing requirements pertaining to health data as well as pseudonymized (i.e., key-coded) data, and imposing additional obligations when we contract third-party processors in connection with the processing of personal data. The GDPR also regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. Transfers of personal data to the United States are subject to increasingly close focus, scrutiny and investigation by the data protection authorities of the EU Member States. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the European Union member states may result in fines of up to the greater of €20 million and 4% of the total worldwide annual turnover of the preceding financial year and other administrative penalties. Compliance with the new data protection rules imposed by GDPR may be onerous and adversely affect our business, financial condition, and results of operations. Further, the GDPR provides that European Union and EEA member states may make their own further laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to use and share personal data or could cause our costs to increase and harm our business and financial condition. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. In June 2021, the Court of Justice of the European Union issued a ruling that expanded the scope of the “one stop shop” under the GDPR. According to the ruling, the competent authorities of EU Member States may, under certain strict

conditions, bring claims to their national courts against a company for breaches of the GDPR, including unlawful cross-border processing activities, even such company does not have an establishment in the EU member state in question and the competent authority bringing the claim is not the lead supervisory authority. From January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR (UK GDPR), which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR (i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global revenue). On June 28, 2021, the European Commission issued an adequacy decision in respect of the UK's data protection framework, enabling data transfers from EU member states to the UK to continue without requiring organizations to put in place contractual or other measures in order to lawfully transfer personal data between the territories. While it is intended to last for at least four years, the European Commission may unilaterally revoke the adequacy decision at any point. It is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. These uncertainties, as well as any applicable regulatory changes, may lead to additional costs and increase our overall risk exposure.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure, or perceived failure, by us to comply with or make effective modifications to our policies, or to comply with any federal, state or international privacy, data-retention or data-protection-related laws, regulations, orders or industry self-regulatory principles could result in proceedings or actions against us by governmental entities or others, a loss of customer confidence, damage to our brand and reputation and a loss of customers, any of which could have an adverse effect on our business. In addition, various federal, state and foreign legislative or regulatory bodies may enact new or additional laws and regulations concerning privacy, data-retention and data-protection issues, including laws or regulations mandating disclosure to domestic or international law enforcement bodies, which could adversely impact our business or our reputation with customers. For example, some countries have adopted laws mandating that some personal information regarding customers in their country be maintained solely in their country. Having to maintain local data centers and redesign product, service and business operations to limit personal information processing to within individual countries could increase our operating costs significantly.

Our employees and independent contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational

harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our business involves the use of hazardous materials, and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and product candidates and other hazardous compounds. We and any third-party manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our third-party manufacturers' facilities pending their use and disposal. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. In such an event, we may be held liable for any resulting damages; such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

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

Our business may be materially adversely affected by the ongoing COVID-19 pandemic.

While the COVID-19 pandemic did not materially adversely affect our business operations during the three months ended March 31, 2022, economic and health conditions in the United States and across most of the globe have changed considerably since the pandemic began. In particular, supply chain disruptions have become a concern for many businesses in the current environment. The COVID-19 pandemic also caused significant volatility in the U.S. and international markets. The impact of the COVID-19 pandemic may increase the possibility of uncertainty in the global financial markets, high inflation and potential for an extended economic downturn. We are subject to inflationary pressures on employee wages, salaries, and the cost of various goods and services that can negatively impact our financial results. We have experienced minor delays in delivery of various products related to our manufacturing processes and in some cases have had to identify new suppliers, which at times resulted in increased costs. While none of the disruptions of our supply chain to date have been material, we cannot exclude the possibility

that further supply chain disruptions due to the COVID-19 pandemic could have a material adverse effect on our business, and the extent to which these issues will impact our results remains uncertain.

In addition to the risk of such supply chain disruptions, as a result of the COVID-19 pandemic, we may also experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- We are conducting a number of clinical trials for product candidates in geographies that have been heavily affected by the COVID-19 pandemic. While the availability of first-generation vaccines in the United States (and other countries) have greatly improved the outlook for the pandemic, we believe that the emergence of variants of concern and/or the potential waning of the immune protection offered by existing vaccines has the potential to lead to prolonging the effects of the pandemic, which could in turn have an impact on various aspects of our clinical trials. For example, with respect to clinical trials for our tumor-specific immunotherapy product candidates, investigators may not want to screen or treat cancer patients with our experimental vaccine and potentially expose them to the novel coronavirus during additional clinic visits. Other potential impacts of the COVID-19 pandemic on our various clinical trials include delays or difficulties in any planned clinical site initiation, including difficulties in obtaining IRB or ethics committee approvals, recruiting clinical site investigators and clinical site staff, delays or difficulties in enrolling patients, interruption of planned key clinical trial activities, such as clinical trial site data monitoring due to diversion of resources at clinical sites or limitation on travel imposed by federal or state governments. This may impact the integrity of subject data.

- While chimpanzee-based adenoviral (ChAd) vaccines have not yet been approved in the US, there is a risk that patient candidates to our GRANITE or SLATE vaccine candidates may become ineligible due to pre-existing neutralizing antibodies to ChAd vaccines, for example following participation in SARS-CoV-2 clinical trials using such vaccines. This in turn could slow down recruitment to our clinical trials, especially if we were to consider expanding our trials in the EU, and, ultimately, if these ChAd vaccines against SARS-CoV-2 are proven effective and become widely available in the general population, may render our vaccination approach unsuitable for many cancer patients. Similarly, patients who have been previously vaccinated with a mRNA-based vaccine may be reluctant to receive our samRNA vaccines, or may have contraindications such as allergic reaction to their SARS-CoV-2, mRNA-based vaccines.

- Because of the COVID-19 pandemic, we have been forced to alter our normal business and operations, for example by encouraging remote work for our employees who, given the nature of their function, can do so effectively. However, many of our employees and contractors perform essential activities that must be completed on-site. While on-site at our facilities, all of our staff are required to wear appropriate personal protective equipment, consistent with public health guidance. The COVID-19 pandemic could disrupt our ability to secure supplies for our facilities and to provide personal protective equipment for our employees. The safety, health and well-being of our workforce is of primary concern, and we may need to enact further precautionary measures to help minimize the risk of our employees being exposed to the novel coronavirus.

- Our increased reliance on personnel working from home may negatively impact productivity or disrupt, delay or otherwise adversely impact our business. In addition, this could increase our cyber-security risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and important agencies and contractors.

- Our employees and contractors conducting research and development activities may not be able to access our laboratories for an extended period of time as a result of the closure of our offices and the possibility that governmental authorities further modify current restrictions.

- The FDA and comparable foreign regulatory agencies may experience operational interruptions or delays, which may impact timelines for regulatory submission, trial initiation and regulatory approval.

- The trading prices for our common shares and other biotechnology companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common shares or such sales may be on unfavorable terms.

While the outlook is improving, the COVID-19 outbreak continues to evolve. Even as vaccination rates continue to grow in the United States and other countries, it remains unclear when the pandemic will subside, particularly if full global vaccination is not achieved or existing vaccines prove less effective against new variants of the virus. The extent to which the outbreak may impact our business, manufacturing, preclinical development activities, preclinical studies and planned clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of COVID-19, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Risks Related to Intellectual Property

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

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our product candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations.

We have applied, and we intend to continue applying, for patents covering aspects of our product candidates, proprietary technologies and their uses that we deem appropriate. However, we may not be able to apply for patents on certain aspects of our current or future product candidates, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition. As of March 31, 2022, our solely owned patent portfolio includes pending patent applications and issued patents. We cannot be certain that the claims in any of our patent applications will be considered patentable by the United States Patent and Trademark Office (USPTO) and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting our product candidates, proprietary technologies and their uses by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;

- other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position;

- any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or product candidates that we may develop;

- because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates, proprietary technologies and their uses;

- an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our or our licensors' applications for any application with an effective filing date before March 16, 2013;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent 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. Moreover, the patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents, if issued, or the patent rights that we license from others, may be challenged in the courts or patent offices in the United States and abroad. Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or

held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our products and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

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

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

- we may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business;
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

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

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

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

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

We rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information. We have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse

engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs, or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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

We currently are reliant upon licenses of certain patent rights and proprietary technology from third parties that is important or necessary to the development of our technology and products, including technology related to our product candidates. For example, we rely on our license agreements with Arbutus and Genevant for certain lipid nanoparticle-based delivery technologies. These and other licenses we may enter into in the future may not provide adequate rights to use such intellectual property and technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to develop and commercialize our technology and products in fields of use and territories for which we are not granted rights pursuant to such licenses.

Licenses to additional third-party technology that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition.

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

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

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

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

Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and future approved products or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexaminations, inter partes review proceedings and post-grant review proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. For example, we are aware of and have timely opposed EP Patent 2569633, expiring in May 2031 (absent any patent term adjustments or extensions), directed to certain methods of identifying and using neoantigens. EP Patent 2569633 is currently validated in Great Britain, France, Germany, Netherlands, Italy, Ireland, Spain and Switzerland. Our opposition was filed in our name on November 7, 2016 by Vossius & Partner. Four other parties also filed oppositions to the patent within the required timeframe. The Opposition Division of the European Patent Office (EPO), held opposition hearings on October 15 and 16, 2018, and determined that EP Patent 2569633 does not meet the requirements of the European Patent Convention (EPC) and consequently, revoked the patent. We received notice in April 2019 that EP Patent 2569633 patentees and licensors filed their appeal to the Opposition Division's decision, and we, along with other opposers, filed responses in August 2019. Opponent Christian Müller withdrew his opposition in May 2020, but the appeal proceedings will be continued between the remaining parties. The EPO scheduled the oral proceedings for the appeal for September 27-28, 2022.

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

the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or product candidates.

As the biotechnology industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties.

Patent applications in the United States and elsewhere are typically published approximately eighteen (18) months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. 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 our product candidates, and cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could:

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

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

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

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

Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. For example, third parties may petition the USPTO for post-grant review within nine (9) months of our patent's issuance date. Further, after the USPTO period for filing post-grant review has expired, third parties may file a petition for inter partes review on certain grounds. Similar mechanisms for challenging the validity and enforceability of a patent exist in ex-U.S. patent offices and may result in the revocation, cancellation, or amendment of any ex-U.S. patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to

the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

We currently have rights to the intellectual property, through licenses from third parties and under patents that we own, to develop our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will depend in part on our ability to acquire, in-license or use these proprietary rights. 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 are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

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

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

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

We are party to various agreements that we depend on to operate our business, including intellectual property rights relating to GRANITE, SLATE and CORAL, in particular, our agreements with Arbutus and Genevant. Our

rights to use currently licensed intellectual property or intellectual property to be licensed in the future are subject to the continuation of and our compliance with the terms of these agreements. Disputes may arise regarding our rights to intellectual property licensed to us from a third party, including but not limited to:

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

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

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

As is common in the biotechnology and biopharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or biopharmaceutical companies including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, 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.

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

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are

ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. 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.

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 GRANITE, SLATE, CORAL or any future product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

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

Our patent rights may be affected by developments or uncertainty in U.S. or ex-U.S. patent statutes, patent case laws in USPTO rules and regulations or in the rules and regulations of ex-U.S. patent offices. There are a number of changes to the U.S. patent laws that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, on September 16, 2011, the Leahy-Smith America Invents Act (Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first to file” system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to

submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings including opposition, derivation, reexamination, inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. This could have a negative impact on some of our intellectual property and could increase uncertainties surrounding obtaining and enforcement or defense of our issued patents. In addition, Congress may pass patent reform legislation that is unfavorable to us. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

Similarly, statutory or judicial changes to the patent laws of other countries may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents.

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

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

The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and if we license intellectual property we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules.

However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

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

- others may be able to make oncology or infectious disease immunotherapies that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Government Regulation

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

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

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP or similar regulations. As such, we and our contract manufacturers will be subject to continual

review and inspections to assess compliance with cGMP or similar regulations and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

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

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

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

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

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, the CARES Act made a number of changes to the Federal Food, Drug and Cosmetic Act aimed at preventing drug shortages. Similarly, the FDA has issued a number of guidance documents describing the agency's expectations for how drug manufacturers should comply with various FDA requirements during the pandemic, including with respect to conducting clinical trials, distributing drug samples, and reporting post-marketing adverse events. Moreover, as a result of the COVID-19 pandemic, there has been increasing political and regulatory scrutiny of foreign-sourced drugs and foreign drug supply chains, resulting in proposed and enacted legislative and executive actions, including Executive Orders, to incentivize or compel drug manufacturing operations to relocate to the United States. It is not clear how these changes and

proposals could impact our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

We may seek orphan drug designation for certain future product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

We may pursue orphan drug designation for certain of our future product candidates. Under the Orphan Drug Act, the FDA may designate a drug or biologic product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the European Commission, on the basis of a scientific opinion by the EMA's Committee for Orphan Medicinal Products (COMP), grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product. In any event, orphan designation is granted only if there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. It is no longer necessary to obtain orphan designation in the UK before an application for marketing authorization is made, and the criteria will be assessed by the MHRA, at the time of assessment of the application for marketing authorization. The criteria in the UK are similar to those in the EU.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax credits for certain clinical trial costs, and application fee waivers. In addition, if an orphan-designated product receives the first FDA approval for the indication for which it has orphan designation (meaning that FDA has not previously approved a drug considered the same drug for same orphan condition), the product is entitled to orphan drug exclusivity. If there is a previously approved same drug for the same orphan condition, to obtain orphan exclusivity, the sponsor of the subsequent drug must demonstrate clinical superiority over the previously approved same drug. If granted, orphan exclusivity means the FDA may not approve any other application to market the same drug for the same disease or condition for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity to meet the needs of the orphan patient population. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval, subject to the positive outcome of the reassessment of the continued compliance with the orphan designation criteria at the time of approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met at the end of the fifth year since grant of the approval, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Moreover, upcoming legislative reforms in the European Union may result in a reduction of market exclusivity periods for orphan medicinal products and/or imposition of additional requirements for grant of such exclusivity. In the UK, if the criteria for orphan designation are met at the time of assessment of the marketing authorization, the applicant is entitled to a fee reduction and ten years of market exclusivity. The terms of market exclusivity, and possibility for the period to be reduced, are similar to those in the EU.

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

Moreover, a recent Eleventh Circuit decision in *Catalyst Pharmaceuticals, Inc. vs. FDA* regarding interpretation of the Orphan Drug Act exclusivity provisions as applied to drugs approved for orphan indications narrower than the drug's orphan designation has the potential to significantly broaden the scope of orphan drug exclusivity for such products. Depending on how broadly FDA applies the Catalystdecision, it could fundamentally change how companies rely on, or seek to work around, orphan drug exclusivity.

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

We have received fast track designation for GRANITE for the treatment of colorectal cancer, and we may seek such designation for some or all of our other product candidates. If a drug or biologic, in our case, is intended for the treatment of a serious or life-threatening disease or condition and the biologic demonstrates the potential to address unmet medical needs for this disease or condition, the biologic sponsor may apply for FDA fast track designation. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development; and, once a BLA is submitted, the product candidate may be eligible for priority review. A fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot guarantee that the FDA would grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Some of our product candidates may require a pediatric development, which may delay our regulatory approvals and ultimately our commercial licensure.

The RACE for Children Act enacted in the U.S. in August 2017 and the European Pediatric Regulation implemented in 2007 as well as similar legislation in the UK may require us to develop our products in pediatric cancer patients. Pediatric cancers are rare, mutational burden is usually low in pediatric tumors and our approach may not be suited for children with cancer, or it may be difficult and slow to accrue children with cancers in our clinical trials. We may incur delays in meeting potential regulatory obligations or require additional investments to fulfill our regulatory commitments, and ultimately may be found incompliant if we cannot deliver pediatric data within the agreed timelines. This could lead to delays in regulatory approval and ultimately commercial licensure of our GRANITE or SLATE products.

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

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

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

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- a licensure framework for follow on biologic products;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

- establishment of a Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Furthermore, the expansion of the 340B Drug Discount Program through the ACA has increased the number of purchasers who are eligible for significant discounts on branded drugs. Several drug manufacturers have commenced litigation, which remains ongoing, challenging the legality of contract pharmacy arrangements under the 340B Drug Discount Program, which may affect the way in which manufacturers are required to extend the 340B Drug Discount Program prices to covered entities, including through contract pharmacies. There are also ongoing challenges regarding the implementation of the 340B Drug Discount Program Administrative Dispute Resolution Process, which is in part intended to resolve claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers. The nature of the current Administrative Dispute Resolution Process, and the outcomes of these court cases, may have a material adverse impact on our revenue should we participate in the 340B Drug Discount Program after receiving approval for our product candidates.

Since its enactment, there have been judicial, Congressional, and executive branch challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through fiscal year 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional action is taken by Congress. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the first six months of the final fiscal year of this sequester. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations. For example, Congress is currently considering a number of bills relating to drug pricing, including bills that would impose rebate obligations for Medicare (and potentially other utilization) for price increases greater than the rate of inflation, require drug pricing negotiations in Medicare, redesign the Part D benefit to lower patient costs and overall spending, and introduce enhanced transparency measures into drug pricing. In particular, the Build Back Better Act, which was enacted by the House of Representatives, introduces drug pricing reforms that would, among other things, allow the federal government to negotiate prices for some high-cost drugs covered under Medicare Parts B and D, introduce inflationary rebates on certain Medicare Part B and

Medicare Part D drugs to support limits on drug price increases in Medicare and private insurance, redesign the structure of the Part D benefit, and require payment of rebates on covered outpatient drugs that are paid for by a state Children's Health Insurance Program. Although the future of the Build Back Better Act is uncertain, there have been additional legislative proposals to enact components of that bill independently -- including those that would affect drug pricing (such as the requirement to pay inflationary rebates in Medicare Parts B and D). Any future drug pricing bills, including provisions that may be drawn from the existing Build Back Better Act, could have a material adverse impact on our business and profitability.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries, hearings and proposed and enacted federal legislation and rules, as well as Executive Orders, designed to, among other things, reduce or limit the prices of drugs and make them more affordable for patients, such as by tying the prices that Medicare reimburses for physician-administered drugs to the prices of drugs in other countries, reform the structure and financing of Medicare Part D pharmaceutical benefits, including through increasing manufacturer contributions to offset Medicare beneficiary costs, bring more transparency to drug pricing rationale and methodologies (including, for example, by requiring drug manufacturers to disclose planned drug price increases and the rationales for such increases), implement data collection and reporting under Section 204 of Title II of Division BB of the Consolidated Appropriations Act, 2021, which requires, among other things, health plans and issuers to disclose rebates, fees, and other remuneration provided by drug manufacturers related to certain pharmaceutical products, enable the government to negotiate prices for drugs covered under Medicare, revise rules associated with the calculation of Medicaid Average Manufacturer Price and Best Price, including the removal of the current statutory 100% of Average Manufacturer Price per-unit cap on Medicaid rebate liability for single source and innovator multiple source drugs effective as of January 1, 2024 under the American Rescue Plan Act of 2021, which may significantly affect the amount of rebates paid on prescription drugs under Medicaid and the prices that are required to be charged to covered entities under the 340B Drug Discount Program, and facilitate the importation of certain lower-cost drugs from other countries. In July 2021, President Biden issued an Executive Order pertaining to drug pricing, which expressed support for legislation allowing direct negotiation in Medicare Part D and inflationary rebates, and directed various executive branch agencies to take actions to lower drug prices and promote generic competition, including directing FDA to support and work with states and Indian Tribes to develop importation plans to import prescription drugs from Canada. The Executive Order required the Secretary of Health and Human Services to develop a comprehensive plan for addressing drug prices. The plan was released on September 9, 2021, and it includes support for legislative and administrative actions that would improve affordability, access and competition, and foster scientific innovation. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the European Union and UK, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European

Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Moreover, upcoming legislative and policy changes in the European Union may further impact the price and reimbursement status of our products in the future.

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act, which prohibit, among other things, including through civil whistleblower or qui tam actions, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;

- the Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;

- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians (as defined by statute), certain non-physician practitioners such as physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives;

- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and

- similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Risks Related to Our Common Stock

Our stock price is volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section of this report and others such as:

- results from, and any delays in, our clinical trials for GRANITE, SLATE, CORAL or any other future clinical development programs, including public misperception of the results of our trials;
- announcements by academic or other third parties challenging the fundamental premises underlying our approach to treating cancer and infectious disease and/or biopharmaceutical product development;
- announcements of regulatory approval or disapproval of our current or any future product candidates;
- failure or discontinuation of any of our research and development programs;
- manufacturing setbacks or delays of or issues with the supply of the materials for our personalized immunotherapy candidate;
- announcements relating to future licensing, collaboration or development agreements, including the early termination or failure of an existing strategic collaboration;
- delays in the commercialization of our current or any future product candidates;
- public misperception regarding the use of our therapies;
- acquisitions and sales of new products, technologies or businesses;
- quarterly variations in our results of operations or those of our current or future competitors;
- changes in earnings estimates or recommendations by securities analysts;
- announcements by us or our competitors of new products, significant contracts, commercial relationships, acquisitions or capital commitments;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- any major changes in our board of directors or management;

- new legislation, particularly in the United States, relating to the sale or pricing of pharmaceuticals;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- product liability claims or other litigation or public concern about the safety of our product candidates;
- market conditions in the biopharmaceutical and biotechnology sectors, particularly as a result of the volatility in the market caused by the COVID-19 pandemic; and
- general economic conditions in the United States and abroad.

In addition, the stock markets in general, and the markets for biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of any particular issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit, and the attention of our management would be diverted from the operation of our business.

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

We may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. For example, in the past, we issued and may, in the future, continue to issue shares in our "at the market offering" programs or other registered offerings under our shelf registration statements or in connection with private placement transactions. To the extent that additional capital is raised through the issuance of shares of common stock or other securities convertible into shares of common stock, our stockholders will be diluted. In addition, future issuances of our common stock or other equity securities (or securities convertible into our common stock or other equity securities), or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or other securities.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of March 31, 2022, we have a total of 72,779,508 shares of common stock outstanding, as well as approximately 13.6 million shares underlying pre-funded warrants and approximately 7.7 million shares of common stock that are subject to outstanding options, restricted stock units or other equity awards. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset a portion of future taxable income, if any, until such unused losses expire, if ever. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (IRC), if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. Any equity financing transactions, private placements and other transactions that occur within a three-year testing period may trigger additional ownership changes, which could further limit our use of such tax

attributes. Any such limitations, whether as a result of prior or future offerings of our common stock or sales of common stock by existing stockholders, could have an adverse effect on our results of operations in our future years.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by our chief executive officer or president or by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

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

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. In addition, our amended and restated certificate of incorporation provides that the U.S. federal district courts are the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim.

General Risk Factors

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

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

As a public company, we are subject to Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404) and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. However, for so long as we remain an

emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. We will remain an emerging growth company until the earlier of (1) December 31, 2023, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th or (4) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

To provide all reports required by these rules we must conduct reviews and testing of our internal controls. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. To report our results of operations and financial statements on an accurate and timely basis, we will depend on third party vendors to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences that would materially harm to our business.

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

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

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

- We will indemnify our directors and officers for serving us in those capacities, or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.

- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

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

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

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

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds

Not applicable.

Issuer Purchases of Equity Securities

Not applicable.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1(a)	Amended and Restated Certificate of Incorporation.	8-K	10/02/2018	3.1	
3.1(b)	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	8-K	05/06/2021	3.1	
3.2	Amended and Restated Bylaws.	8-K	05/06/2021	3.2	
4.1	Reference is made to exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	09/17/2018	4.2	
4.3	Description of Common Stock.	10-K	03/10/2022	4.3	
31.1	Certification of Chief Executive Officer of Gritstone bio, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.				X
31.2	Certification of Chief Financial Officer of Gritstone bio, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.				X
32.1*	Certification by the Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350).				X
101.INS	Inline XBRL Instance Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 has been formatted in Inline XBRL.				X

* The certification attached as Exhibit 32.1 that accompanies this report is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Gritstone bio, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this 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.

Gritstone bio, Inc.

Date: May 5, 2022

By: /s/ Andrew Allen
Andrew Allen, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Vassiliki Economides
Vassiliki Economides
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Allen, M.D., Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Gritstone bio, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 5, 2022

By: /s/ Andrew Allen

Andrew Allen, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vassiliki Economides, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Gritstone bio, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 5, 2022

By: /s/ Vassiliki Economides
Vassiliki Economides
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Gritstone bio, Inc. (the "Company") for the period ended March 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Andrew Allen, M.D., Ph.D., President and Chief Executive Officer (Principal Executive Officer) of the Company, and Vassiliki Economides, Chief Financial Officer (Principal Financial Officer) of the Company, respectively, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 5, 2022

/s/ Andrew Allen
Andrew Allen, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 5, 2022

/s/ Vassiliki Economides
Vassiliki Economides
Chief Financial Officer
(Principal Financial Officer)