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 June 30, 2019

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 Oncology, 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.)**
5858 Horton Street, Suite 210 Emeryville, California	**94608**
(Address of Principal Executive Offices)	**(Zip Code)**

(510) 871-6100
(Registrant's Telephone Number, Including Area Code)

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.

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**

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

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

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

As of August 9, 2019, there were 35,773,598 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Gritstone Oncology, Inc.
Condensed Balance Sheets
(Unaudited)

(In thousands, except share and per share amounts)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 107,728	$ 52,183
Marketable securities	73,511	100,927
Prepaid expenses and other current assets	3,458	4,526
Total current assets	184,697	157,636
Property and equipment, net	18,966	29,494
Operating lease right-of-use assets	21,309	—
Deposits and other long-term assets	2,700	2,428
Long-term marketable securities	508	—
Total assets	$ 228,180	$ 189,558
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,253	$ 4,825
Accrued compensation	2,621	3,951
Accrued liabilities	1,803	992
Lease liabilities, current portion	2,890	—
Deferred revenue, current portion	5,498	5,340
Total current liabilities	18,065	15,108
Deferred rent, net of current portion	—	1,353
Other non-current liabilities	—	12
Lease financing obligation, net of current portion	—	10,490
Lease liabilities, net of current portion	16,919	—
Deferred revenue, net of current portion	10,818	13,473
Total liabilities	45,802	40,436
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Convertible preferred stock, $0.0001 par value; 10,000,000 shares authorized at June 30, 2019 and December 31, 2018; no shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized at June 30, 2019 and December 31, 2018; 35,654,631 and 28,823,130 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	17	16
Additional paid-in capital	348,021	275,593
Accumulated other comprehensive income (loss)	76	(85)
Accumulated deficit	(165,736)	(126,402)
Total stockholders' equity	182,378	149,122
Total liabilities and stockholders' equity	$ 228,180	$ 189,558

See accompanying notes to the unaudited condensed financial statements.

Gritstone Oncology, Inc.
Condensed Statements of Operations and Comprehensive Loss
(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration revenue	$ 1,150	$ —	$ 2,497	$ —
Operating expenses:				
Research and development	18,529	12,689	34,428	24,090
General and administrative	4,835	2,814	9,212	4,852
Total operating expenses	23,364	15,503	43,640	28,942
Loss from operations	(22,214)	(15,503)	(41,143)	(28,942)
Interest income, net	1,042	31	1,962	94
Net loss	(21,172)	(15,472)	(39,181)	(28,848)
Other comprehensive loss:				
Unrealized gain on marketable securities, net of tax	9	58	161	43
Net and comprehensive loss	$ (21,163)	$ (15,414)	$ (39,020)	$ (28,805)
Net loss per share, basic and diluted	$ (0.63)	$ (6.57)	$ (1.25)	$ (12.62)
Weighted-average number of shares used in computing net loss per share, basic and diluted	33,582,844	2,353,337	31,273,696	2,285,906

See accompanying notes to the unaudited condensed financial statements.

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

(In thousands, except share amounts)

Three Months Ended June 30, 2019:

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at March 31, 2019	—	$ —	29,024,382	$ 16	$ 276,703	$ 67	$ (144,564)	$ 132,222
Issuance of common stock upon public offering at $11.50 per share for cash, net of issuance costs of $556			6,500,000	$ 1	$ 69,708			69,709
Unrealized loss on marketable securities, net of tax	—	—	—	—	—	9	—	9
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	49,563	—	17	—	—	17
Issuance of common stock upon exercise of stock options	—	—	80,686	—	276	—	—	276
Stock-based compensation	—	—	—	—	1,317	—	—	1,317
Net loss	—	—	—	—	—	—	(21,172)	(21,172)
Balance at June 30, 2019	—	$ —	35,654,631	$ 17	$ 348,021	$ 76	$ (165,736)	$ 182,378

Three Months Ended June 30, 2018:

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at March 31, 2018	17,797,529	$ 156,937	2,264,024	$ 1	$ 2,440	$ (89)	$ (75,003)	$ 84,286
Issuance of Series C convertible preferred stock at $13.04 per share for cash, net of issuance costs of $71	690,128	8,928	—	—	—	—	—	8,928
Unrealized loss on marketable securities, net of tax	—	—	—	—	—	58	—	58
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	109,515	—	38	—	—	38
Issuance of common stock upon exercise of stock options	—	—	30,725	1	14	—	—	15
Issuance of common stock for consulting services			4,347	—	36			36
Stock-based compensation	—	—	—	—	783	—	—	783
Net loss	—	—	—	—	—	—	(15,472)	(15,472)
Balance at June 30, 2018	18,487,657	$ 165,865	2,408,611	$ 2	$ 3,311	$ (31)	$ (90,475)	$ 78,672

Continued on next page.

See accompanying notes to the unaudited condensed financial statements.

Gritstone Oncology, Inc.
Condensed Statements of Stockholders' Equity - Continued
(Unaudited)

(In thousands, except share amounts)

Six Months Ended June 30, 2019:

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2018	—	$ —	28,823,130	$ 16	$ 275,593	$ (85)	$ (126,402)	$ 149,122
Cumulative effect of adopting new accounting standard (Note 2)	—	—	—	—	—	—	(153)	(153)
Issuance of common stock upon public offering at $11.50 per share for cash, net of issuance costs of $556			6,500,000	$ 1	$ 69,708			69,709
Unrealized gain on marketable securities, net of tax	—	—	—	—	—	161	—	161
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	100,877	—	34	—	—	34
Issuance of common stock upon exercise of stock options	—	—	230,624	—	362	—	—	362
Stock-based compensation	—	—	—	—	2,324	—	—	2,324
Net loss	—	—	—	—	—	—	(39,181)	(39,181)
Balance at June 30, 2019	—	$ —	35,654,631	$ 17	348,021	76	(165,736)	182,378

Six Months Ended June 30, 2018:

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2017	17,797,529	$ 156,937	2,152,525	$ 1	$ 2,045	$ (74)	$ (61,627)	$ 97,282
Issuance of Series C convertible preferred stock at $13.04 per share for cash, net of issuance costs of $71	690,128	8,928	—	—	—	—	—	8,928
Unrealized loss on marketable securities, net of tax	—	—	—	—	—	43	—	43
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	172,563	—	60	—	—	60
Issuance of common stock upon exercise of stock options	—	—	38,919	1	20	—	—	21
Exercise of common stock warrants			40,257	—	13			13
Issuance of common stock for consulting services			4,347	—	36			36
Stock-based compensation	—	—	—	—	1,137	—	—	1,137
Net loss	—	—	—	—	—	—	(28,848)	(28,848)
Balance at June 30, 2018	18,487,657	$ 165,865	2,408,611	$ 2	$ 3,311	$ (31)	$ (90,475)	$ 78,672

See accompanying notes to the unaudited condensed financial statements.

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

(In thousands)

	Six Months Ended June 30,	
	2019	**2018**
Operating activities		
Net loss	$ (39,181)	$ (28,848)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,130	1,882
Net amortization of premiums and discounts on marketable securities	(970)	(180)
Stock-based compensation	2,324	1,173
Non-cash operating lease expense	2,837	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	268	415
Deposits and other long-term assets	(272)	74
Accounts payable	(867)	(177)
Accrued compensation	(1,329)	(434)
Accrued and other non-current liabilities	1,312	(765)
Deferred rent	—	(206)
Lease liability	(1,293)	—
Deferred revenue	(2,497)	—
Net cash used in operating activities	(37,538)	(27,066)
Investing activities		
Purchase of marketable securities	(16,012)	—
Maturities of marketable securities	44,050	20,220
Purchase of property and equipment	(4,831)	(2,857)
Net cash provided by investing activities	23,207	17,363
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	70,432	24
Payments of deferred financing costs	(556)	(779)
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	8,992
Net cash provided by financing activities	69,876	8,237
Net increase/(decrease) in cash, cash equivalents and restricted cash	55,545	(1,466)
Cash, cash equivalents and restricted cash at beginning of period	53,175	39,999
Cash, cash equivalents and restricted cash at end of period	$ 108,720	$ 38,533
Supplemental disclosures of non-cash investing and financing information		
Property and equipment purchases accrued but not yet paid	$ 2,775	$ 247
Deferred financing costs included in accrued liabilities and accounts payable	$ —	$ 345

See accompanying notes to the unaudited condensed financial statements.

Gritstone Oncology, Inc.
Notes to Condensed Financial Statements
(Unaudited)

1. Organization

Description of Business

Gritstone Oncology, Inc. ("Gritstone" or the "Company") is an immuno-oncology company developing personalized cancer immunotherapies to fight multiple cancer types. The Company was incorporated in the state of Delaware on August 5, 2015, and is based in Emeryville, California and Cambridge, Massachusetts, with a manufacturing facility in Pleasanton, California. The Company operates in one segment.

Public Offerings

In October 2018, the Company closed its initial public offering ("IPO"), of 6,854,202 shares of common stock, including 187,535 shares sold pursuant to the underwriters' partial exercise of their option to purchase additional shares, at an offering price to the public of $15.00 per share. The Company received net proceeds of approximately $92.6 million, after deducting underwriting discounts and commissions and offering costs. In connection with the IPO, all of the Company's outstanding shares of convertible preferred stock were automatically converted into 19,409,132 shares of common stock. The related carrying value of $177.9 million was reclassified to common stock and additional paid-in capital.

In connection with the completion of its IPO, on October 2, 2018, the Company's certificate of incorporation was amended and restated to provide for 300,000,000 authorized shares of common stock with a par value of $0.0001 per share and 10,000,000 authorized shares of preferred stock with a par value of $0.0001 per share.

In April 2019, the Company completed an underwritten public offering and sold and issued an aggregate of 6,500,000 shares of common stock at a price to the public of $11.50 per share. The Company received aggregate net proceeds from the offering of approximately $69.7 million, after deducting underwriting discounts and commissions and offering costs.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

The condensed 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 financial statements should be read in conjunction with the Company's financial statements as of and for the year ended December 31, 2018, which are included in the Company's Annual Report on Form 10-K, as filed with the SEC on March 28, 2019.

Reverse Stock Split

On September 20, 2018, the Company amended and restated its amended and restated certificate of incorporation to effect a 1-for-6.9 reverse split ("Reverse Split") of shares of the Company's common and convertible preferred stock. The par value and the authorized shares of common stock and convertible preferred stock were not adjusted as a result of the Reverse Split. All of the share and per share information included in the accompanying financial statements has been adjusted to reflect the Reverse Split.

Need for Additional Capital

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 cash, cash equivalents, and marketable securities of $181.7 million and $153.1 million as of June 30, 2019 and December 31, 2018, respectively. The Company had an accumulated deficit of $165.7 million and $126.4 million as of June 30, 2019 and December 31, 2018, respectively. The Company had net losses of $21.2 million and $39.2 million for the three and six months ended June 30, 2019, respectively, and $15.5 million and $28.8 million for the three and six months ended June 30, 2018, respectively, and net cash used in operating activities of $37.5 million and $27.1 million for the six months ended June 30, 2019 and 2018,

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 contracts with customers. The Company has evaluated and concluded there are no conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for a period of one year following the date that these condensed financial statements are issued. Management expects operating losses to continue for the foreseeable future. As a result, the Company will need to raise additional capital. If sufficient funds on acceptable terms are not available when needed, the Company could be required to significantly reduce its operating expenses and delay, reduce the scope of, or eliminate one or more of its development programs. Failure to manage discretionary spending or raise additional financing, as needed, may adversely impact the Company's ability to achieve its intended business objectives.

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 assets and liabilities as of the date of the condensed financial statements and the reported amounts of revenue and expenses in the condensed financial statements and accompanying notes during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, clinical and preclinical study trial accruals, fair value of assets and liabilities the present value of lease liabilities and the corresponding right-of-use assets ("ROU assets"), 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.

Other Risks and Uncertainties

The Company is subject to a number of risks similar to those of other early-stage immuno-oncology 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 product candidates. 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.

Cash, Cash Equivalents, and Restricted Cash

Cash equivalents, which consist primarily of highly liquid investments with maturities of three months or less when purchased, are stated at cost which approximates 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 a letter of credit under a lease agreement which has been collateralized by a cash deposit for an equal amount and is recorded within deposits and other long-term assets on the balance sheet based on the term of the underlying lease. The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the balance sheets that sum to the total of the same amounts shown in the statements of cash flows (in thousands).

	June 30, 2019	December 31, 2018
Cash and cash equivalents	$ 107,728	$ 52,183
Restricted cash	992	992
Total cash, cash equivalents and restricted cash	$ 108,720	$ 53,175

Leases

Prior to January 1, 2019, the Company rented its office space and facilities under non-cancelable operating lease agreements and recognizes related rent expense on a straight-line basis over the term of the lease. The Company's lease agreements contained rent holidays, scheduled rent increases, and renewal options. Rent holidays and scheduled rent increases were included in the determination of rent expense to be recorded ratably over the lease term. The Company did not assume renewals in its determination of the lease term unless they were deemed to be reasonably assured at the inception of the lease. The Company began recognizing rent expense on the date that it obtained the legal right to use and control the leased space. Deferred rent consisted of the difference between cash payments and the recognition of rent expense on a straight-line basis for the buildings the Company occupied.

Funding of leasehold improvements by the Company's landlord was accounted for as a tenant improvement allowance and recorded as current and non-current deferred rent liabilities and amortized on a straight-line basis as a reduction of rent expense over the term of the lease.

In certain arrangements, the Company was involved in the construction of improvements to buildings it was leasing. To the extent the Company was involved with the structural improvements of the construction project or takes construction risk, the Company was considered to be the owner of the building and related improvements for accounting purposes during the construction period. The

Company recorded the fair value of the building and related improvements subject to the lease within property and equipment on the balance sheet. The Company also recorded a corresponding lease financing obligation on its balance sheet representing the amounts financed by the lessor for the building and lessor financed improvements. Lessor financed improvement incentives due but not yet received of $1.2 million at December 31, 2017 were recorded as prepaid expense and other current assets on the condensed balance sheet. Such amounts were fully collected in April 2018. Once a construction project was complete, the Company considered the requirements for sale-leaseback accounting treatment. If the Company concluded the arrangement did not qualify for sale-leaseback accounting treatment, the building and related improvements remained on the Company's condensed balance sheet and were subject to depreciation and assessment of impairment.

For such arrangements, at both pre and post the construction period, the Company bifurcated its lease payments into a portion allocated to the building and a portion allocated to the parcel of land on which the building had been built. The portion of the lease payments allocated to the land was treated for accounting purposes as operating lease payments, and therefore was recorded as rent expense in the condensed statements of operations and comprehensive loss. The portion of the lease payments allocated to the building were further bifurcated into a portion allocated to interest expense and a portion allocated to reduce the lease financing obligation. The interest rate used for the lease financing obligation represented the Company's estimated incremental borrowing rate at the inception of the lease, adjusted to reduce any built in loss.

Subsequent to January 1, 2019, 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. All 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 our condensed balance sheet at June 30, 2019. The Company has elected not to recognize on the condensed balance sheet 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 utilizes the appropriate incremental borrowing rate, which is the rate 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 right-of-use asset 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 noncancelable 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 to not 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 balance sheet and amortized as lease expense on a straight-line basis over the lease term.

Revenue Recognition

The Company analyzes its collaboration agreements 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 customer guidance. For elements of collaboration arrangements that are accounted for pursuant to the revenue from contracts with customer guidance, an appropriate recognition method is determined and applied consistently, generally by analogy 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 balance sheets. If the related performance obligation is expected to be satisfied within the next twelve months this will be classified in current liabilities. Amounts recognized as revenue prior to receipt are recorded as contract assets in the Company's balance sheets. If the Company expects to have an unconditional right to receive consideration in the next twelve 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 deliverable 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 deliverable.

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.

Recently Issued Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU No. 2016-13"), which requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. ASU No. 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The new standard will be effective on January 1, 2020. Early adoption is permitted. The Company is currently evaluating the effect that the updated standard will have on its financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement.* ASU No. 2018-13 eliminates, adds and modifies certain disclosure requirements for fair value measurements and requires companies to disclose certain information. The new standard will be effective for fiscal years, and interim periods within those year, beginning after December 15, 2019. The Company is currently evaluating the impact of adopting this accounting update on its financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles (Topic 350): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This new standard also requires customers to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. This standard is effective for annual reporting periods beginning after December 15, 2019, and interim periods within that year. This new standard can be applied either retrospectively

or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the impact of adoption on its financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* , which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. The standard adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606, and requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The standard is effective for interim and annual periods beginning after December 15, 2019, with early adoption permitted, including adoption in any interim period for public business entities for periods in which financial statements have not been issued. Amendments in the standard should be applied retrospectively to the date of initial application of Topic 606, but entities may elect to apply the amendments in this Update retrospectively either to all contracts or only to contracts that are not completed at the date of initial application of Topic 606, and should disclose the election. An entity may also elect to apply the practical expedient for contract modifications that is permitted for entities using the modified retrospective transition method in Topic 606. The Company is currently assessing the impact of this standard on its condensed financial statements.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842).* The new standard requires the recognition of lease liabilities and ROU assets on the balance sheet arising from lease transactions at the lease commencement date and the disclosure of key information about leasing arrangements. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842) Targeted Improvements*, which provides an additional transition method in which the new lease standard is applied at the adoption date and recognized as a cumulative-effect adjustment to retained earnings without adjustment to comparative periods (collectively "Topic 842"). The amendment has the same effective date and transition requirements as the new lease standard.

The Company adopted this standard on January 1, 2019 using the modified retrospective approach and elected the package of practical expedients permitted under transition guidance, which allowed the Company to carry forward its historical assessments of: 1) whether contracts are or contain leases, 2) lease classification and 3) initial direct costs, where applicable. The Company did not elect the practical expedient allowing the use-of-hindsight which would require the Company to reassess the lease term of its leases based on all facts and circumstances through the effective date and did not elect the practical expedient pertaining to land easements as this is not applicable to the current contract portfolio. The Company elected the post-transition practical expedient to not separate lease components from non-lease components for all existing lease classes. The Company also elected a policy of not recording leases on its condensed balance sheets when the leases have a term of 12 months or less and the Company is not reasonably certain to elect an option to purchase the leased asset.

The impact of the adoption of Topic 842 on the accompanying condensed balance sheet as of January 1, 2019 was as follows (in thousands):

	December 31, 2018	Adjustments due to Adoption of Topic 842	January 1, 2019
Property and equipment, net	$ 29,494	$ (14,524)	$ 14,970
Operating lease right-of-use assets	$ -	$ 14,224	$ 14,224
Operating liabilities:			
Lease liabilities, current portion	$ -	$ 2,200	$ 2,200
Accrued liabilities	$ 992	$ (475)	$ 517
Deferred rent, net of current portion	$ 1,353	$ (1,353)	$ -
Lease financing obligation, net of current portion	$ 10,490	$ (10,490)	$ -
Lease liabilities, net of current portion	$ -	$ 8,980	$ 8,980
Accumulated deficit	$ (126,402)	$ (153)	$ (126,555)

The adjustments due to the adoption of Topic 842 primarily related to the recognition of operating lease ROU Assets and lease liabilities for the Company's operating leases. In addition, the adoption of Topic 842 resulted in a change in classification of build-to-suit component of our lease in Pleasanton, California to an operating lease and resulted in the derecognition of the $15.4 million capitalized building and related accumulated depreciation of $0.9 and $10.5 million financing lease obligation, as the Company had been deemed to own the building under legacy GAAP (Note 6). The Company also recorded an insignificant reduction to opening accumulated deficit as

of January 1, 2019 as a result of the adoption of Topic 842.

The impact of the adoption of Topic 842 on the accompanying condensed statements of operations was not material.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, *Disclosure Update and Simplification*. These amendments eliminate, modify, or integrate into other SEC requirements certain disclosure rules. Among the amendments is the requirement to present an analysis of changes in stockholders' equity in the interim financial statements included in quarterly reports on Form 10-Q. The analysis, which can be presented as a footnote or separate statement, is required for the current and comparative quarter and year-to-date interim periods. The amendments are effective for all filings made on or after November 5, 2018. In light of the anticipated timing of effectiveness of the amendments and expected proximity of effectiveness to the filing date for most filers' quarterly reports, the SEC's Division of Corporate Finance issued a Compliance and Disclosure Interpretation related to Exchange Act Forms, or CDI – Question 105.09, that provides transition guidance related to this disclosure requirement. CDI – Question 105.09 states that the SEC would not object if the filer's first presentation of the changes in shareholders' equity is included in its Form 10-Q for the quarter that begins after the effective date of the amendments. As such, the Company adopted these SEC amendments on November 5, 2018 and has presented the analysis of changes in stockholders' equity in its interim financial statements in this Form 10-Q for the quarter ending June 30, 2019. Adoption of these SEC amendments did not have a material effect on the Company's financial position, results of operations, cash flows or stockholders' equity.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU No. 2018-07"). ASU No. 2018-07 is intended to reduce cost and complexity and to improve financial reporting for share-based payments issued to non-employees (for example, service providers, external legal counsel, suppliers, etc.). The ASU expands the scope of Topic 718, *Compensation—Stock Compensation*, which currently only includes share-based payments issued to employees, to also include share-based payments issued to non-employees for goods and services. Consequently, the accounting for share-based payments to non-employees and employees will be substantially aligned. ASU No. 2018-07 is effective for annual and interim periods beginning after December 15, 2018. Early adoption of the standard is permitted. The standard will be applied in a retrospective approach for each period presented. The Company adopted the standard during the quarter ended March 31, 2019, which did not have a material impact on its financial statements and related disclosures.

3. Cash Equivalents and Marketable Securities

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

	June 30, 2019			
Description	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term marketable securities:				
Money market funds	$ 95,242	$ —	$ —	$ 95,242
Commercial paper	36,287	45	—	36,332
Corporate debt securities	37,148	31	—	37,179
Total short-term marketable securities	168,677	76	$ —	168,753
Long-term marketable securities:				
Corporate debt securities	508	—	—	508
Total	$ 169,185	$ 76	$ —	$ 169,261
Classified as:				
Cash equivalents				$ 95,242
Marketable securities				74,019
Total				$ 169,261

Description	December 31, 2018 Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term marketable securities:				
Money market funds	$ 36,148	$ —	$ —	$ 36,148
Commercial paper	45,244	—	(40)	45,204
Corporate debt securities	67,815	1	(46)	67,770
Total	$ 149,207	$ 1	$ (86)	$ 149,122
Classified as:				
Cash equivalents				$ 48,195
Marketable securities				100,927
Total				$ 149,122

All marketable securities held as of June 30, 2019, had contractual maturities of less than two years. There have been no realized gains or losses on marketable securities for the periods presented. None of the Company's investments in marketable securities has been in an unrealized loss position for more than one year. The Company determined that it has the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery, thus there has been no recognition of any other-than-temporary impairment in the three and six months ended June 30, 2019 and 2018.

See Note 4 for further information regarding the fair value of our financial instruments.

4. Fair Value Measurements

The Company determines the fair value of financial and non-financial assets and liabilities based on the assumptions that market participants would use in pricing the asset or liability in orderly transaction between market participants at the measurement date. The identification of market participant assumptions provides a basis for determining what inputs are to be used for pricing each asset or liability. A fair value hierarchy has been established which gives precedence to fair value measurements calculated using observable inputs over those using unobservable inputs. This hierarchy prioritizes the inputs into three broad levels as follows:

- 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.

The carrying amounts reflected on the 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.

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

Description	June 30, 2019 Total	Level 1	Level 2	Level 3
Short-term marketable securities:				
Money market funds	$ 95,242	$ 95,242	$ —	$ —
Commercial paper	36,332	—	36,332	—
Corporate debt securities	37,179	—	37,179	—
Total short-term marketable securities	168,753	95,242	73,511	—
Long-term marketable securities:				
Corporate debt securities	508	—	508	—
Total	$ 169,261	$ 95,242	$ 74,019	$ —

Description	December 31, 2018 Total	Level 1	Level 2	Level 3
Short-term marketable securities:				
Money market funds	$ 36,148	$ 36,148	$ —	$ —
Commercial paper	45,204	—	45,204	—
Corporate debt securities	67,770	—	67,770	—
Total	$ 149,122	$ 36,148	$ 112,974	$ —

The Company measures the fair value of money market funds based on quoted prices in active markets for identical securities. Commercial paper and corporate debt securities are valued taking into consideration valuations obtained from third-party pricing services. The 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):

	June 30, 2019	December 31, 2018
Computer equipment and software	$ 634	$ 470
Furniture and fixtures	974	935
Laboratory equipment	18,797	16,406
Leasehold improvements	3,081	3,063
Buildings and related improvements capitalized under a lease financing transaction	—	15,371
Construction in progress	3,514	—
	27,000	36,245
Less accumulated depreciation and amortization	(8,034)	(6,751)
Total property and equipment, net	$ 18,966	$ 29,494

Depreciation and amortization expense was $1.1 million and $2.1 million for the three and six months ended June 30, 2019, respectively, and $1.0 million and $1.9 million for the three and six months ended June 30, 2018, respectively.

6. Commitments and Contingencies

Leases

In November 2015, the Company entered into an 84-month non-cancelable operating lease, effective March 2016, for a facility in Emeryville, California, with laboratory and office space. In conjunction with signing the lease, the Company paid a cash security deposit of $50,000. The lease agreement includes an escalation clause for increased rent and a renewal provision allowing the Company to extend this lease for an additional three years at the prevailing rental rate. In September 2018 the Emeryville lease was amended whereby the Company entered into a 12-month operating lease for additional temporary space. The Company may terminate the temporary space lease agreement with 30 days advanced written notice to the landlord.

In January 2019, the Company entered into a 120-month operating lease for a new facility in Emeryville, California with office and laboratory space for the Company's new principal executive offices. In conjunction with signing the lease, the Company paid a cash security deposit of $0.6 million, which is recorded as a deposit on the Company's condensed balance sheet as of June 30, 2019. The lease agreement 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's obligation to pay rent will commence on November 1, 2019. The Company has determined the tenant improvements to be lessee owned and therefore has recorded a $10.2 million ROU Asset and a $10.9 million lease liability on the condensed balance sheet as of June 30, 2019.

In connection with the new lease agreement, the Company also entered into an agreement (the "Lease Termination Agreement") to early terminate the Company's existing lease dated November 2015, for its current premises. The current lease will terminate effective no later than 60 days after the rent commencement date under the new lease, which in October 2019. The Company accounted for the Lease Termination Agreement as a separate contract and recorded an adjustment of $1.8 million, which is included within the June 30, 2019 condensed balance sheet, to the ROU Asset and lease liability to reflect the remaining term of the modified agreement through October 2019.

In February 2016, the Company entered into a 67-month non-cancelable operating lease effective October 2016 for a facility in Cambridge, Massachusetts, with laboratory and office space. In conjunction with signing the lease, the Company paid a cash security deposit of $0.3 million, which is recorded in deposits and other long term assets on the Company's condensed balance sheet as of June 30, 2019. The lease agreement includes an escalation clause for increased rent and a renewal provision allowing the Company to extend

this lease for an additional three years at the prevailing rental rate. The lessor provided the Company a tenant improvement allowance for a total of $2.1 million to complete the laboratory and office renovation. The Company recorded the tenant allowance received as leasehold improvements under the property and equipment account and deferred rent liability on the accompanying condensed balance sheets. Upon adoption of Topic 842, the deferred rent liability was reclassified against the ROU Asset on the condensed balance sheet as of January 1, 2019.

In March 2017, the Company entered into a noncancelable operating lease (the "Pleasanton Lease") to lease 42,620 square feet of office, cleanroom, and laboratory support manufacturing space in Pleasanton, California (the "Pleasanton Facility"). Subsequently, in April 2017, the Company took possession of the space. The Pleasanton Lease includes a free rent period, escalating rent payments and a term that expires on November 30, 2024. The Company has the option to extend the lease term for a period of five years at the then market rental rate. The Company's obligation to pay rent commenced in December 2017. 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 all of its obligations. The letter of credit may be reduced based on certain levels of cash and cash equivalents the Company holds. 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 for the Pleasanton Facility. The scope of the tenant improvements did not qualify under the lease accounting guidance as "normal tenant improvements" and the Company was deemed owner of the leased building during the construction period for accounting purposes. The Company had therefore capitalized the $9.3 million fair value of the leased building within property and equipment, net, and recognized a corresponding non-current lease financing obligation in the condensed balance sheet as of December 31, 2018. The fair value of the leased building was estimated using a market approach that utilized comparable observable sales for similar assets (Level 2 inputs). The Company had also recognized building improvements totaling $6.1 million for additions to the leased building incurred by the Company during the construction period, of which $1.2 million were due but had not yet been received from the landlord as of December 31, 2017 and were recorded as an increase to the lease financing obligation and prepaid and other current assets on the condensed balance sheet at that time. Such amounts were subsequently reimbursed by the landlord in April 2018. In November 2017, construction on the Pleasanton Facility was substantially completed and the leased property was placed into service. The Company determined the completed construction project did not qualify for sale-leaseback accounting due to the collateral held by the landlord in the form of a letter of credit and instead was accounted for as a financing lease transaction. The leased building for the Pleasanton Facility and related improvements remained on the Company's balance sheet as of December 31, 2018 and rental payments associated with the Pleasanton Lease were allocated to operating lease expense for the ground underlying the leased building and principal and interest payments on the lease financing obligation.

Upon adoption of Topic 842, the Company analyzed the Pleasanton lease under the new guidance and determined that the lease would be classified as an operating lease under legacy GAAP. Additionally, given the Company had previously recognized the building and financing lease obligation solely as a result of the transactions build to suit designation under legacy GAAP, the Company derecognized the $14.5 million leased building and $10.5 million lease financing obligation from the condensed balance sheet on January 1, 2019. The unamortized tenant improvement allowance of $4.0 million and was recognized as a component of ROU Assets on January 1, 2019. The Company also recorded a $0.2 million reduction to opening accumulated deficit as of January 1, 2019.

In September 2018, the Company entered into a 24-month non-cancellable operating lease for an additional facility in Cambridge, Massachusetts with laboratory and office space. In conjunction with signing the lease, the Company prepaid the first twelve months base rent in the amount of $1.3 million, of which the remaining amount of $0.9 million as of January 1, 2019 was reclassified to the ROU Asset on the condensed balance sheet upon adoption of Topic 842. The Company also paid a cash security deposit of $0.3 million, which included $0.1 million for the last month's rent and was reclassified to the ROU Assets on the condensed balance sheet upon adoption of Topic 842 on January 1, 2019. The remaining security deposit is recorded in deposits and other long term assets on the Company's condensed balance sheet as of June 30, 2019.

In May 2019, the Company entered into a 64-month non-cancellable operating lease for additional office space in Pleasanton, California. The lessor provided the Company a tenant improvement allowance for a total of $0.1 million to complete the office renovation. The Company's obligation to pay rent will commence on August 1, 2019. The Company has determined the tenant improvements to be lessee owned and therefore has recorded a $0.3 million ROU Asset and a $0.3 million lease liability on the condensed balance sheet as of June 30, 2019.

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 statements of operations and comprehensive loss, were as follows (in thousands):

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Lease cost		
Operating lease cost	$ 1,493	$ 2,837
Short-term lease cost	65	122
Total lease cost	$ 1,558	$ 2,959

Supplemental information related to leases was as follows (in thousands):

	Six Months Ended June 30, 2019
Cash paid for amounts included in the measurement of lease liabilities (in thousands):	
Operating cash flows from operating leases	$ 1,293
New right-of-use assets obtained in exchange for lease obligations (in thousands):	
Operating leases	$ 342
Weighted average remaining lease term (years):	
Operating leases	7.3
Weighted average discount rate:	
Operating leases	9.0%

As of June 30, 2019, minimum annual rental payments under the Company's operating lease agreements are as follows (in thousands):

	Operating Leases
Year ending December 31:	
2019 (remaining six months)	$ 1,751
2020	5,170
2021	4,383
2022	3,742
2023	3,459
Thereafter	15,979
Total minimum payments	$ 34,484
Less: Amounts representing interest	(10,529)
Less: Amounts representing tenant improvement allowance	(4,146)
Present value of future minimum lease payments	19,809
Less: Current portion of lease liability	(2,890)
Noncurrent portion of lease liability	$ 16,919

The amounts representing the tenant improvement allowance are expected to be received by the Company concurrent with the completion of construction in late 2019.

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 drug candidates. Under the agreement, the Company paid an upfront payment of $0.5 million to the CRO. The upfront payment was capitalized and recognized as research and development expense using the straight-line method over the term of the agreement, which is one year and ended on December 31, 2018. During the year ended December 31, 2018, the Company recognized a total of $1.1 million of research and development expense under the agreement. The Company is 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 June 30, 2019. During the three and six months ended June 30, 2019, the Company recognized an insignificant amount of research and development expense under the agreement. During the three and six months ended June 30, 2018, the Company recognized a total of $0.4 million and $0.7 million, respectively, of research and development expense under the agreement.

In May 2019, the Company entered into a contract research and testing agreement with a third-party contract research organization to provide antibody discovery related services. Under the agreement, the Company paid an upfront payment of $0.1 million

to the CRO. The upfront payment was capitalized and recognized as research and development expense as the services are delivered. The Company is also 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 June 30, 2019. During the three and six months ended June 30, 2019, the Company recognized a total of $0.4 million of research and development expense under the agreement.

Guarantees and Indemnifications

The Company, as permitted under Delaware law and in accordance with its certification 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, 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):

	June 30, 2019	December 31, 2018
Prepaid research and development-related expenses	$ 1,848	$ 1,789
Prepaid insurance	333	966
Prepaid rent	—	860
Interest and other receivables	888	462
Other	389	449
Total prepaid expenses and other current assets	$ 3,458	$ 4,526

Deposits and Other Long-Term Assets

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

	June 30, 2019	December 31, 2018
Lease security deposit	$ 1,055	$ 632
Restricted cash	992	992
Prepaid research and development-related expenses	553	554
Other	100	250
Total deposits and other long-term assets	$ 2,700	$ 2,428

Accrued Liabilities

Accrued current liabilities consist of the following (in thousands):

	June 30, 2019	December 31, 2018
Deferred rent	$ —	$ 445
Research and development-related expenses	998	252
Other	805	295
Total accrued current liabilities	$ 1,803	$ 992

8. Collaboration and License Agreements

bluebird bio, Inc.

In August 2018, the Company entered into a Research Collaboration and License Agreement ("Collaboration Agreement") with bluebird bio, Inc. ("bluebird"). Under the terms of the Collaboration Agreement, the Company will provide to bluebird 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 bluebird 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 Collaboration Agreement, bluebird 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 IPO. In October 2018, bluebird 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 Collaboration 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 Collaboration Agreement. None of these events had occurred as of June 30, 2019 and no royalties were due from the sale of licensed products.

bluebird may terminate the Collaboration 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 Gritstone on a licensed product. The Collaboration 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 bluebird under the licensed intellectual property will remain in effect in accordance with their respective terms. Additionally, all of bluebird's payment obligations that have not yet accrued related to future milestone and royalty payments will be reduced by fifty percent for the remainder of the agreement term.

The Company concluded that bluebird is a customer, and the contract is not subject to accounting literature on collaborative arrangements. This is because the Company granted to bluebird 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 Collaboration Agreement: 1) transfer of a license to intellectual property and related technology know-how ("License and Know-How"); 2) the obligation to perform target selection and TCR generation services ("Research and Development Services"); and 3) participation on the Joint Steering Committee ("JSC"). The Company provided to bluebird 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 agreement because bluebird is dependent on the Company to execute the Research and Development Services and participate on the JSC in order for bluebird 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. As such, 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 which are contingent upon bluebird reaching various milestones are not considered performance obligations at the inception of the arrangement.

The transaction price at the inception of the Collaboration Agreement consisted of the upfront payment of $20.0 million and the $10.0 million received from bluebird 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 June 30, 2019. 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 bluebird'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 bluebird. 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 contract 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. We analyzed the impact of bluebird terminating the agreement prior to August 2023 and determined that there were substantive non-monetary penalties to bluebird for doing so. We considered quantitative and qualitative factors to reach this conclusion.

Revenue is recognized when, or as, the Company satisfies its performance obligation by transferring the promised services to bluebird. Revenue will be 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 bluebird. 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.

For the three and six months ended June 30, 2019, the Company has recognized $1.2 million and $2.5 million, respectively, as collaboration revenue as a result of satisfying its performance obligation by transferring the promised services estimated by the labor cost incurred. A deferred revenue balance of $16.3 million is recorded on the condensed balance sheet in both current and long-term liabilities as of June 30, 2019, which relates to the performance obligation identified, with such amounts to be recognized over the period the performance obligation is expected to be satisfied, which is currently expected to be through mid-2023.

Changes in the deferred revenue balance during the six months ended June 30, 2019 are as follows (in thousands):

	Deferred Revenue
Balance at January 1, 2019	$ 18,813
Additions	—
Deductions	(2,497)
Balance at June 30, 2019	$ 16,316

There were no receivables or net contract assets recorded as of June 30, 2019 associated with the Collaboration Agreement.

The Company expensed all incremental costs of obtaining the Collaboration Agreement as such amounts were insignificant.

Arbutus Biopharma Corporation

In October 2017, the Company entered into an Exclusive License Agreement by and between Arbutus Biopharma Corporation ("Arbutus") and Protiva Biotherapeutics Inc. a wholly owned subsidiary of Arbutus. Certain terms of the agreement were modified by amendment in July 2018. Under the license agreement, the Company has an exclusive license to utilize certain Arbutus intellectual property including patents and know-how relating to immunotherapy. Under this license agreement, the Company paid an upfront payment of $5.0 million which was included in research and development expenses during 2017. The Company also reimbursed Arbutus for materials and personnel costs totaling $0.2 million, which were included in research and development expenses during 2017. During the three and six months ended June 30, 2019, the Company reimbursed Arbutus for $0.1 million and $0.2 million, respectively, for materials and personnel costs. During the three and six months ended June 30, 2018, the Company reimbursed Arbutus for $0.2 million and $0.3 million, respectively, for materials and personnel costs. The Company is obligated to pay Arbutus certain milestone payments up to $123.5 million on achievement of specified events, and royalties of not more than 3.5% on sales of its licensed products. Following the acceptance of our investigational new drug application for GRANITE-001 by the U.S. Food and Drug Administration, the Company made a $2.5 million development milestone payment to Arbutus in September 2018 that was recorded as research and development expense. None of the other events had occurred as of June 30, 2019 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-001, GO-004, in December 2018 the Company recorded $50,000 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 June 30, 2019 and no royalties were due from the sales of licensed products. The Company also issued a ten-year warrant to the cancer center for the right to purchase 40,257 shares of its common stock at $0.35 per share. The estimated fair value of the warrant was not significant and was included in research and development expense and additional paid-in-capital. The warrant was exercised in full in January 2018.

9. Convertible Preferred Stock and Common Stock

Convertible Preferred Stock

The Company's Series A, Series B and Series C convertible preferred stock has various features, including convertibility and non-cumulative dividends. The Company determined that none of the features required bifurcation from the underlying shares, either because they are clearly and closely related to the underlying shares or because they do not meet the definition of a derivative. The Series

A, Series B and Series C convertible preferred stock are considered permanent equity and have not been accreted up to their redemption value. The Second and Third Tranche rights are considered to be mutual options as neither the purchasers nor the Company have a commitment or obligation to purchase or sell additional shares. As such, these rights are not accounted for separately. Moreover, in any such redemption (i.e. deemed liquidation) all equity holders (common and preferred) will receive the same form of consideration. The preferred stockholders cannot contractually redeem their shares, or redeem their shares through separate negotiation, without the Company's common stockholders being able to also redeem their shares for the same form of consideration.

The Company entered into a Series C preferred stock purchase agreement ("Series C Preferred Stock Purchase Agreement"), with certain investors in June 2018, and upon approval by the Company's Board of Directors, the Company completed a Series C convertible preferred stock financing ("Series C") at a price per share of $13.04. The net cash proceeds totaled $8.9 million and 690,128 shares of Series C convertible preferred stock were issued. Issuance costs totaled $0.1 million and were recorded as a reduction of the proceeds. In July 2018, the Company sold an additional 153,360 shares of Series C convertible preferred stock at a price of $13.04 per share for net cash proceeds of $2.0 million. In August 2018, in conjunction with the Collaboration Agreement entered into with bluebird, the Company sold bluebird 768,115 shares of Series C convertible preferred stock at a price of $13.04 per share for gross proceeds of $10.0 million.

In October 2018, upon closing of the IPO, all outstanding shares of convertible preferred stock converted into 19,409,132 shares of common stock. Per the terms of the Company's Amended and Restated Certificate of Incorporation, the shares of outstanding convertible preferred stock converted at the election of the holders of at least a majority of the then outstanding shares of convertible preferred stock, voting together as a single class and on an as-converted to common stock basis.

At June 30, 2019 and December 31, 2018, there were 10,000,000 shares of convertible preferred stock authorized and no shares were outstanding.

Prior to the conversion of the convertible preferred stock upon closing of the IPO in October 2018, the rights, preferences, and privileges of the convertible preferred stock were as follows:

Redemption Rights

The preferred stock is not redeemable by holders unless a redemption event occurs. A redemption event will only occur upon the liquidation or winding up of the Company, a greater than 50% change in control, or the sale of substantially all of the assets of the Company. Management has also elected not to adjust the carrying values of the Series A, Series B and Series C convertible preferred stock to the redemption value of such shares, since it is uncertain whether or when a redemption event will occur. Subsequent adjustments to increase the carrying value to the redemption values will be made when it becomes probable that such a redemption will occur.

Dividends Rights

The holders of Series A, Series B and Series C convertible preferred stock are entitled to receive dividends, from any assets legally available, prior and in preference to any declaration or payment of any dividend to the common stockholders, at the rate of 8% of the original issue price (as determined on a per annum basis and on an as-converted basis). Such dividends are payable if and when declared by the Board of Directors and are not cumulative. After payment of such dividends, any additional dividends shall be distributed among the holders of the Series A, Series B and Series C convertible preferred stock and common stock pro rata based on the number of shares of common stock then held by each holder (assuming conversion of all such preferred stock into common stock). No such dividends were ever declared or accrued.

Liquidation Rights

In the event of any liquidation, dissolution, or winding up of the Company, whether voluntary or involuntary ("Liquidation Event"), the holders of Series C convertible preferred stock are entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of the Series A and B convertible preferred stock, $13.04 per share (as adjusted for any stock splits, combinations, reorganizations, or similar transactions, plus any declared and unpaid dividends). The holders of Series B convertible preferred stock are entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of the Series A convertible preferred stock, $10.76 per share (as adjusted for any stock splits, combinations, reorganizations, or similar transactions, plus any declared and unpaid dividends). After payment of the above, the holders of Series A convertible preferred stock are entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of common stock, $6.90 per share (as adjusted for any stock splits, combinations, reorganizations, or similar transactions, plus any declared and unpaid dividends).

If, upon the occurrence of such an event, the proceeds to be distributed are insufficient to permit the payment to such holders of the full preferential amounts, then the entire amount legally available for distribution shall be distributed among the holders of the Series

A, Series B and Series C preferred stock in proportion to the full preferential amount that each such holder is otherwise entitled to receive had such proceeds been available.

After liquidation preference payments have been made to the holders of the convertible preferred stock as described above, all of the remaining assets and funds of the Company are to be distributed ratably among the holders of the preferred and common stock, as if the preferred stock had been converted to common stock. However, Series C preferred stock holders are limited to the greater of (1) $65.21 per share (as adjusted for any stock splits, combinations, reorganizations or similar transactions) and (2) the amount the holder would have received if all shares of Series C convertible preferred stock had been converted to common stock prior to such liquidation, dissolution, or winding up of the Company. Series B preferred stockholders are limited to the greater of (1) $53.82 per share (as adjusted for any stock splits, combinations, reorganizations or similar transactions) and (2) the amount the holder would have received if all shares of Series B convertible preferred stock had been converted to common stock prior to such liquidation, dissolution, or winding up of the Company. Series A preferred stockholders are limited to the greater of (1) $34.50 per share (as adjusted for any stock splits, combinations, reorganizations or similar transactions) and (2) the amount the holder would have received if all shares of Series A convertible preferred stock had been converted to common stock prior to such liquidation, dissolution, or winding up of the Company.

Voting Rights

Except as otherwise required by law, the holders of common and Series A, Series B and Series C convertible preferred stock vote together as a single class. The holders of the convertible preferred stock are entitled to the number of votes equal to the number of shares of common stock into which the convertible preferred stock could be converted on the record date for the vote, or upon the written consent of the stockholders.

The holders of the Series A convertible preferred stock are entitled to elect three directors of the Company, the holders of the Series B convertible preferred stock are entitled to elect one director of the Company, and the holders of common stock shall be entitled to elect one director of the Company.

Conversion Rights

Each share of Series A, Series B and Series C convertible preferred stock, at the option of the holder and at any time after the date of issuance, is convertible into the number of shares of common stock determined by dividing the respective original issue price by the conversion price (the Conversion Price). The Company's Series A, Series B, and Series C Conversion Prices were $6.90, $10.76, and $13.04, respectively, and were subject to certain future adjustments.

As part of the Company's Series C convertible preferred stock financing, the Company's certificate of incorporation was amended to reduce the public offering automatic conversion price for the Series A and B convertible preferred stock from $21.53 to $15.66 per share. The Company accounted for this as a modification of an instrument akin to equity that resulted in no incremental fair value being attributed to the Series A and Series B convertible preferred stock.

Common Stock

The Company is authorized to issue 300,000,000 shares of common stock. Holders of common stock are generally entitled to one vote per share on all matters to be voted upon by the stockholders of the Company.

Subject to the preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Board of Directors. No dividends have been declared to date.

10. Stock-Based Compensation

Award Incentive Plans

In August 2015, the Board of Directors approved the 2015 Equity Incentive Plan ("2015 Plan"). In February 2018, the Company's Board of Directors approved a 507,246 share increase in the number of shares to be reserved under the Company's 2015 Equity Incentive Plan. In connection with the Company's IPO and the effectiveness of the 2018 Award Incentive Plan ("2018 Plan"), the 2015 Plan terminated and no further awards will be granted under the 2015 Plan. The 92,815 shares of common stock shares that were then unissued and available for future issuance under the 2015 Plan became available under the 2018 Plan. The 2015 Plan will continue to govern all outstanding awards by their existing terms.

In September 2018, the Company's Board of Directors approved the 2018 Plan. Under the 2018 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other certain awards to individuals who are employees, officers, directors or consultants of the Company. A total of 2,690,000 shares of our common stock are initially reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, or SARs,

restricted stock awards, restricted stock unit awards and other stock-based awards, 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 our stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's Board of Directors. The maximum number of shares that may be issued upon the exercise of ISOs under the 2018 Plan is 45,000,000.

Prior to the Company's IPO, the grant date fair value of the Company's common stock was determined by the Company's Board of Directors with the assistance of management and an independent third-party valuation specialist. The grant date fair value of the Company's common stock was determined using valuation methodologies which utilizes certain assumptions including probability weighting of events, volatility, time to liquidation, a risk-free interest rate and an assumption for a discount for lack of marketability (Level 3 inputs). In determining the fair value of the Company's common stock, the methodologies used to estimate the enterprise value of the Company were performed using methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation ("AICPA Accounting and Valuation Guide").

Subsequent to the Company's IPO, the grant date fair value of each share of common stock underlying stock option awards is based on the closing price of our common stock as reported by the Nasdaq Select Global Market on the date of grant of the award.

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.

2018 Employee Stock Purchase Plan

In September 2018, the Company's board of directors approved the 2018 Employee Stock Purchase Plan ("2018 ESPP"). The 2018 ESPP became effective on September 28, 2018. A total of 282,334 shares were initially reserved for issuance under the 2018 ESPP. Additionally, the number of shares of common stock reserved for issuance under the 2018 ESPP will increase automatically each year, beginning on January 1, 2019 and continuing through and including January 1, 2028, by the lesser of (1) 1% of the shares of common stock outstanding on December 31 of the preceding calendar year or (2) such lesser number of shares determined by the Company's board of directors. The maximum number of shares that may be issued under the 2018 ESPP is 5,000,000. The offering periods are scheduled to start on the first trading day on or after June 1 or December 1 of each year. Contributions under the 2018 ESPP are limited to a maximum of 15% of an employee's eligible compensation.

The estimated fair value of stock purchase rights granted under the ESPP were calculated using the Black-Scholes option-pricing model using the following assumptions:

	Three and Six Months Ended June 30,
	2019
Expected dividend yield	— %
Expected term	0.5 years
Risk-free interest rate	2.31%
Expected volatility	77%

Valuation of Stock Options

The fair value of each stock option granted to an employee or a director was estimated as of the date of grant using the Black-Scholes model with the following weighted-average assumptions:

	Three Months Ended June 30,	Six Months Ended June 30,	
	2019	2019	2018
Expected dividend yield	— %	— %	—%
Expected term	6.00 years	6.03 years	6.07 years
Risk-free interest rate	2.09%	2.50%	2.65%
Expected volatility	85%	86%	89%

There were no options granted for the three months ended June 30, 2018.

Using the Black-Scholes model, the weighted-average grant-date fair value of employee stock options granted was $7.08 for the three months ended June 30, 2019 and $8.62 and $2.37 per share during the six months ended June 30, 2019, and 2018, respectively.

Stock Option Activity

A summary of the 2015 Plan and 2018 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, 2018	2,695,110	2,429,859	$ 5.31	8.86	$ 25,646
Authorized	1,160,000	—			
Granted	(992,048)	992,048	$ 11.76		
Exercised	—	(230,624)	$ 1.57		
Cancelled	152,585	(152,585)	$ 8.33		
Repurchased	11,680	—	$ 0.35		
Balance at June 30, 2019	3,027,327	3,038,698	$ 7.55	8.81	$ 13,347
Vested and exercisable – June 30, 2019		784,201	$ 3.48	8.18	$ 6,053
Vested and expected to vest – June 30, 2019		2,987,908	$ 7.15	8.71	$ 14,176

For the six months ended June 30, 2019 and 2018, the total intrinsic value of stock option awards exercised was $2.6 million and $0.3 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.

At June 30, 2019, $13.7 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 3.15 years. The total fair value of shares vested during the period ended June 30, 2019 was $1.2 million.

Stock-based compensation expense and awards granted to non-employees were not material for either the three months ended June 30, 2019 or June 30, 2018.

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development expenses	$ 862	$ 319	$ 1,557	$ 595
General and administrative expenses	455	500	767	578
Total	$ 1,317	$ 819	$ 2,324	$ 1,173

11. Net Loss Per Common Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss for each period presented.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Numerator:				
Net loss	$ (21,172)	$ (15,472)	$ (39,181)	$ (28,848)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	33,582,844	2,353,337	31,273,696	2,285,906
Net loss per share, basic and diluted	$ (0.63)	$ (6.57)	$ (1.25)	$ (12.62)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods 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:

	Three and Six Months Ended June 30,	
	2019	2018
Convertible preferred stock	—	18,487,657
Options issued and outstanding and ESPP shares issuable and outstanding	3,045,526	1,667,674
Early exercised common stock subject to future vesting	114,410	336,608
Total	3,159,936	20,491,939

12. Subsequent Events

In July 2019, the Company amended its Cambridge, Massachusetts laboratory and office space facility lease. The amendment extended the original 24 month lease term ending in August 2020 by another 12 months through August 2021. Upon six months written notice, the Company has the right to terminate the amended lease agreement. The amendment provides for annual base rent of approximately $3.4 million, effective July 2019.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the condensed financial statements and notes thereto included elsewhere in this report and with the audited financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2018. This discussion and analysis and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "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 are an immuno-oncology company developing tumor-specific cancer immunotherapies to fight multiple cancer types. Our approach harnesses the natural power of a patient's own immune system to recognize short tumor-specific peptide sequences presented on cancer cells, referred to as tumor-specific neoantigens, or TSNA, in order to destroy tumor cells. Our tumor-specific immunotherapy treatment is built on two key pillars—first, our proprietary Gritstone EDGE platform, which gives us a superior ability to predict, from a routine tumor biopsy, the TSNA that are presented on a patient's tumor cells; and second, our ability to develop and manufacture potent immunotherapies utilizing patients' TSNA to drive the patient's immune system to attack and destroy tumors.

We initiated a first-in-human Phase 1/2 clinical trial of GRANITE-001, our first personalized immunotherapy product candidate, in the fourth quarter of 2018, evaluating it in the treatment of common solid tumors, including metastatic non-small cell lung cancer and gastroesophageal, bladder and colorectal cancers, in each case in combination with checkpoint inhibitors provided by our collaborator, Bristol-Myers Squibb Company, or BMS. We dosed our first patient in this trial, GO-004, in the first quarter of 2019. The Phase 1 portion of the GO-004 Phase 1/2 trial will seek to establish a dose for further investigation in Phase 2 and to evaluate safety, tolerability and, importantly, immunogenicity of our product candidate. We will seek to further evaluate efficacy and safety in the Phase 2 cohort expansion portion in several common solid tumor types.

Our second tumor-specific product candidate series, SLATE, will utilize the same antigen delivery system as GRANITE-001 but contains a fixed cassette with TSNA that are shared across a subset of cancer patients rather than a cassette unique to an individual patient, providing us with an off-the-shelf alternative to our personalized manufactured product candidate, GRANITE-001. The U.S. Food and Drug Administration, or FDA, allowed the Investigational New Drug application, or IND, for SLATE-001 to proceed in June 2019 and we have initiated a Phase 1/2 clinical trial of SLATE-001, GO-005, in combination with immune checkpoint inhibitors for the treatment of patients with advanced solid tumors, including metastatic non-small cell lung cancer, pancreatic cancer and colorectal cancer. Our patient screening protocol is open at several clinical sites to expedite early identification of eligible patients for treatment in GO-005.

We are developing a second immunotherapy platform targeting shared tumor antigens, including shared TSNA, which relies upon bispecific antibodies, or BiSAb, targeting solid tumors. BiSAb have been shown by others to exhibit early evidence of efficacy in B cell malignancies, using B cell-specific targets such as CD19, CD20 and BCMA, and our goal is to extend this concept into the treatment of solid tumors using our novel approach to identify tumor-specific antigens and antibody fragments against such targets. Our BiSAb approach uses an antibody fragment to recognize a tumor antigen and, in the same molecule, a different antibody fragment to recognize immune effector cells such as CD3+ T cells. These therapeutics aim to refocus immune effector cells specifically upon the tumor through antibody-driven recognition of tumor-specific antigens. We use our EDGE platform to identify novel solid tumor-specific antigens and develop antibody fragments that bind tightly and with high specificity to these targets. These antibody fragments are deployed within a bispecific antibody framework to form novel "drug-in-a-bottle" therapeutic candidates. We expect this program to generate a development candidate in the second half of 2019.

We have funded our operations to date primarily from private placements of our convertible preferred stock, the net proceeds from our initial public offering, or IPO, which we completed in October 2018, and from our follow-on public offering, which we completed in April 2019, as well as cash proceeds from bluebird under the collaboration agreement we entered into in August 2018, or the bluebird Collaboration Agreement. We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration agreements with third parties. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. GRANITE-001, SLATE-001 and the BiSAb program will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. In addition, we expect to incur additional costs associated with operating as a public company. We also do not yet have a sales organization or commercial infrastructure and, accordingly, we will incur significant expenses to develop a sales organization or commercial infrastructure in advance of generating any commercial product sales. As a result, we will need substantial additional capital to support our operating activities.

We currently anticipate that we will seek to fund our operations through equity or debt financings or other sources, such as potential collaboration agreements with third parties. Adequate funding may not be available to us on acceptable terms, or at all. If sufficient funds on acceptable terms are not available when needed, we will be required to significantly reduce our operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs.

Manufacturing is a vital component of personalized immunotherapy, and we have invested significantly in our manufacturing facility, which opened in November 2017. We currently use a hybrid approach to manufacturing our personalized immunotherapy wherein certain elements of our product candidates are manufactured on an outsourced basis at qualified third-party contract manufacturing organizations, or CMOs, and other elements of our product candidates are manufactured internally. Our goal is to internalize the majority of the manufacturing steps to drive down both cost and production time, as well as establish full control over intellectual property and product quality, which will require significant investments in our manufacturing facility and processes.

Since we commenced operations in August 2015, we have invested a significant portion of our efforts and financial resources in research and development activities and establishing our manufacturing facility. We have incurred net losses each year since inception. Our net losses were $21.2 million and $39.2 million for the three and six months ended June 30, 2019 and $15.5 million and $28.8 million for the three and six months ended June 30, 2018, respectively. As of June 30, 2019, we had an accumulated deficit of $165.7 million, and we do not expect positive cash flows from operations in the foreseeable future. We do not have any products approved for sale. We expect to continue to incur net operating losses for at least the next several years as we advance our personalized cancer immunotherapy 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.

In October 2018, we completed our IPO and sold and issued an aggregate of 6,854,202 shares of our common stock, including 187,535 shares sold pursuant to the underwriters' partial exercise of their option to purchase additional shares, at a price to the public of $15.00 per share. We received aggregate net proceeds from the offering of $92.6 million, after deducting underwriting discounts and commissions and offering costs.

In April 2019, we completed an underwritten public offering and sold and issued an aggregate of 6,500,000 shares of common stock at a price to the public of $11.50 per share. We received aggregate net proceeds from the offering of approximately $69.7 million, after deducting underwriting discounts and commissions and offering costs.

Components of Our Operating Results

Collaboration Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the foreseeable future. For the three and six months ended June 30, 2019, we recognized $1.2 million and $2.5 million, respectively, of revenue from the bluebird Collaboration Agreement. No revenue was recognized for the three or six months ended June 30, 2018.

In the future, we will continue to recognize revenue from the bluebird Collaboration Agreement and may generate revenue from product sales or other collaboration agreements, strategic alliances and licensing arrangements. We expect that our revenue will 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 arrangement 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.

In October 2017, we entered into a license agreement with Arbutus Biopharma Corporation, or Arbutus. Certain terms of the agreement were modified by amendment in July 2018. Under the agreement, Arbutus grants 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. Under this agreement, we made an upfront payment of $5.0 million, which was included in research and development expenses during the year ended December 31, 2017. Following the acceptance of our investigational new drug application for GRANITE-001 by the U.S. Food and Drug Administration, we made a $2.5 million development milestone payment to Arbutus in September 2018 that was recorded as research and development expense. During the three and six months ended June 30, 2019, we reimbursed Arbutus for $0.1 million and $0.2 million, respectively, for materials and personnel costs. During the three and six months ended June 30, 2018, we reimbursed Arbutus for $0.2 million and $0.3 million, respectively, for materials and personnel costs.

We expect our research and development expenses to increase substantially in the future as we advance our cancer immunotherapy 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.

Due to the early-stage nature of our personalized cancer immunotherapy programs, we do not track costs on a project-by-project basis. As our programs enter clinical studies, we intend to track the costs of each program.

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, and interest expense on our lease financing obligation, which was derecognized on January 1, 2019 in connection with our adoption of ASU No. 2016-02, *Leases (Topic 842)*.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2019 and 2018

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

	Three Months Ended June 30,		
	2019	2018	Change
Collaboration revenue	$ 1,150	$ —	$ 1,150
Operating expenses:			
Research and development	18,529	12,689	5,840
General and administrative	4,835	2,814	2,021
Total operating expenses	23,364	15,503	7,861
Loss from operations	(22,214)	(15,503)	(6,711)
Interest income, net	1,042	31	1,011
Net loss	$ (21,172)	$ (15,472)	$ (5,700)

	Six Months Ended June 30,		
	2019	2018	Change
Collaboration revenue	$ 2,497	$ —	$ 2,497
Operating expenses:			
Research and development	34,428	24,090	10,338
General and administrative	9,212	4,852	4,360
Total operating expenses	43,640	28,942	14,698
Loss from operations	(41,143)	(28,942)	(12,201)
Interest income, net	1,962	94	1,868
Net loss	$ (39,181)	$ (28,848)	$ (10,333)

Collaboration Revenue

Collaboration revenue was $1.2 million and $2.5 million, respectively for the three and six months ended June 30, 2019. No collaboration revenue was recognized for the three or six months ended June 30, 2018. The increase was due to recognition of revenue during the period pursuant to the bluebird Collaboration Agreement which we entered into in August 2018.

Research and Development Expenses

Research and development expenses were $18.5 million and $34.4 million for the three and six months ended June 30, 2019 compared to $12.7 million and $24.1 million for the three and six months ended June 30, 2018, respectively.

The increase of $5.8 million for the three months ended June 30, 2019 compared to the three months ended June 30, 2018 was primarily due to increases in personnel related expenses, expenses related to outside services and consultants, in-house laboratory supplies and consumables, and facilities expenses. Personnel related costs increased by $1.6 million, as a direct result of our increased research and development headcount. Outside services and consultants increased by $1.2 million for clinical trials, preclinical testing and contract manufacturing expansion. In-house expenses for laboratory supplies and consumables increased by $1.3 million, and reflect our increased research and development personnel. Facility related expenses increased by $1.6 million to accommodate our manufacturing expansion and increased research and development personnel and due to our adoption of Topic 842 and the change in accounting treatment related to the Pleasanton lease, whereby the full rental payment on this lease is treated as an operating expense post January 1, 2019. Milestone and license payments increased $0.1 million to reflect payments made under certain agreements.

The increase of $10.3 million for the six months ended June 30, 2019 compared to the six months ended June 30, 2018 was primarily due to increases in personnel related expenses, expenses related to outside services and consultants, in-house laboratory supplies and consumables, and facilities expenses. Personnel related costs increased by $3.4 million, as a direct result of our increased research and development headcount. Outside services and consultants increased by $2.0 million for clinical trials, preclinical testing and contract manufacturing expansion. In-house expenses for laboratory supplies and consumables increased by $2.2 million, and reflect our increased research and development personnel. Facility related expenses increased by $2.5 million to accommodate our manufacturing expansion and increased research and development personnel and due to our adoption of Topic 842 and the change in accounting treatment related to the Pleasanton lease, whereby the full rental payment on this lease is treated as an operating expense post January 1, 2019. Milestone and license payments increased $0.2 million to reflect payments made under certain agreements.

General and Administrative Expenses

General and administrative expenses were $4.8 million for the three months ended June 30, 2019 compared to $2.8 million for the three months ended June 30, 2018. The increase of $2.0 million was primarily attributable to a $0.5 million increase in personnel related costs as we expanded our headcount, and a $1.3 million increase in outside services for legal, finance, recruiting and other professional services to support our ongoing operations and operate as a public company. Facility related expenses increased by $0.2 million to accommodate our increased general and administrative personnel.

General and administrative expenses were $9.2 million for the six months ended June 30, 2019 compared to $4.9 million for the six months ended June 30, 2018. The increase of $4.4 million was primarily attributable to a $1.3 million increase in personnel related costs as we expanded our headcount, and a $2.8 million increase in outside services for legal, finance, recruiting and other professional services to support our ongoing operations and operate as a public company. Facility related expenses increased by $0.3 million to accommodate our increased general and administrative personnel.

Interest Income, Net

Interest income, net was $1.0 million for the three months ended June 30, 2019 compared to $31,000 for the three months ended June 30, 2018. The income for both years represents interest and investment income from cash, cash equivalents and marketable securities. The increase of $1.0 million was due to a higher average cash, cash equivalents and marketable securities balance in 2019 than in 2018 and decreased interest expense incurred on our lease financing obligation due to our adoption of Topic 842 and the change in accounting treatment related to the Pleasanton lease.

Interest income, net was $2.0 million for the six months ended June 30, 2019 compared to $94,000 for the six months ended June 30, 2018. The income for both years represents interest and investment income from cash, cash equivalents and marketable securities. The increase of $1.9 million was due to a higher average cash, cash equivalents and marketable securities balance in 2019 than in 2018 and decreased interest expense incurred on our lease financing obligation due to our adoption of Topic 842 and the change in accounting treatment related to the Pleasanton lease.

Liquidity and Capital Resources

Sources of Liquidity

From our inception through June 30, 2019, we have funded our operations primarily through private placements of our convertible preferred stock, our Collaboration Agreement with bluebird, and the proceeds of our IPO and follow on public offering. We have raised net cash proceeds of $177.9 million from the issuance of our convertible preferred stock and a non-refundable upfront payment of $20.0 million from bluebird.

In October 2018, we completed our initial public offering by issuing 6,854,202 shares of our common stock, including 187,535 shares sold pursuant to the underwriters' partial exercise of their option to purchase additional shares, at an offering price of $15.00 per share, for net proceeds of approximately $92.6 million, after deducting underwriting discounts and commissions and offering costs.

In April 2019, we completed an underwritten public offering and sold and issued an aggregate of 6,500,000 shares of common stock at a price to the public of $11.50 per share. We received aggregate net proceeds from the offering of approximately $69.7 million, after deducting underwriting discounts and commissions and offering costs.

As of June 30, 2019, we had cash, cash equivalents, and marketable securities of $181.7 million and an accumulated deficit of $165.7 million, compared to cash, cash equivalents, and marketable securities of $153.1 million and an accumulated deficit of $126.4 million as of December 31, 2018.

Additionally, 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, preclinical studies and providing general and administrative support for these operations. We expect to continue to incur net operating losses for at least the next several years as we advance GRANITE-001, SLATE-001, the BiSAb program and 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.

Future Funding Requirements

We do not have any products approved for sale, and we have never generated any revenue from contracts with customers. 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 collaboration agreements with third parties, and we do not know when, or if, either will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our current and future product candidates, and begin to commercialize any approved products. 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 expect to incur additional 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 our tumor- specific immunotherapy product candidates or from collaboration or license agreements with third parties, if ever, we expect to finance our future cash needs through public or private equity offerings or debt financings. 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 $165.7 million through June 30, 2019. 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 12 months. 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 tumor-specific immunotherapy product candidates, and conducting preclinical studies and clinical trials, including our Phase 1/2 clinical trial of GRANITE-001, which we initiated in the fourth quarter of 2018;
- the scope, progress, results and costs of conducting studies and clinical trials for our SLATE product candidate series, including the Phase 1/2 clinical trial for SLATE-001, which we initiated in mid-2019;
- the scope, progress, results, and costs of conducting drug discovery, preclinical studies and clinical trials for our BiSAb program, for which we expect to select a product candidate in the second half of 2019;
- the timing of, and the costs involved in, obtaining regulatory approvals for our tumor-specific immunotherapy 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 agreements;
- the cost of manufacturing our tumor-specific immunotherapy 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 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.

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):

	Six Months Ended June 30,	
	2019	2018
Cash used in operating activities	$ (37,538)	$ (27,066)
Cash provided by investing activities	23,207	17,363
Cash provided by financing activities	69,876	8,237
Net decrease in cash and cash equivalents	$ 55,545	$ (1,466)

Cash Used in Operating Activities

During the six months ended June 30, 2019, cash used in operating activities was $37.5 million, which consisted of a net loss of $39.2 million, adjusted by non-cash charges of $6.3 million and cash used due to changes in our operating assets and liabilities of $4.6 million. The non-cash charges consisted primarily of depreciation and amortization expense of $2.1 million, stock-based compensation of $2.3 million, and non-cash operating lease expense of $2.8 million, offset by $0.9 million net amortization of premiums and discounts on marketable securities. The change in our operating assets and liabilities was primarily due to a decrease of $1.3 million in accrued compensation, primarily as a result of the payment of bonuses, a decrease of $2.5 million in deferred revenue as a result of revenue recognized during the six months ended June 30, 2019, a decrease of $1.3 million in the lease liability as a result of lease payments made, a decrease of $0.9 million in accounts payable, and a decrease in deposits and other long-term assets of $0.2 million, offset by an increase of $1.3 million in accrued an other non-current liabilities and an increase of $0.3 in prepaid expenses and other current assets.

During the six months ended June 30, 2018, cash used in operating activities was $27.1 million, which consisted of a net loss of $28.8 million, adjusted by non-cash charges of $2.9 million and cash used due to changes in our operating assets and liabilities of $1.1 million. The non-cash charges consisted primarily of depreciation and amortization expense of $1.9 million and stock-based compensation of $1.2 million, offset by $0.2 million amortization of marketable securities. The change in our operating assets and liabilities was primarily due to a decrease of $0.4 million in accrued compensation and a decrease of $0.8 million in accrued and other liabilities and deferred rent.

Cash Provided By Investing Activities

During the six months ended June 30, 2019, cash provided by investing activities was $23.2 million, which consisted of $16.0 million in proceeds from the maturity of marketable securities offset by $44.1 million in purchases of marketable securities and $4.8 million of capital expenditures to purchase property and equipment.

During the six months ended June 30, 2018, cash provided by investing activities was $17.4 million, which consisted of $20.2 million in proceeds from the maturity of marketable securities, offset by $2.9 million of capital expenditures to purchase property and equipment.

Cash Provided by Financing Activities

During the six months ended June 30, 2019, cash provided by financing activities was $69.9 million, which primarily consisted of $70.3 million in proceeds from the issuance of common stock in a public offering and $0.2 million of proceeds from the exercise of stock options, offset by $0.6 million of payments of deferred financing costs.

During the six months ended June 30, 2018, cash provided by financing activities was $8.2 million and consisted primarily of $9.0 million of proceeds from the issuance of convertible preferred stock, offset by $0.8 million payments of deferred IPO costs.

Since our inception through June 30, 2019, we have raised an aggregate of approximately $177.9 million through the issuance and sale of shares of our convertible preferred stock, net of $0.4 million in issuance costs, which we have used to fund our operations.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements, as defined under U.S. Securities and Exchange Commission rules.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of June 30, 2019 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases(1)	$ 34,484	$ 1,751	$ 9,553	$ 7,201	$ 15,979
Total obligations	$ 34,484	$ 1,751	$ 9,553	$ 7,201	$ 15,979

(1) See Note 6 to our condensed 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. In September 2018, we made a milestone payment of $2.5 million in relation to a license agreement. During the three and six months ended June 30, 2019 and 2018 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 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 personalized immunotherapy candidate in the treatment of cancer. Under the agreement, we paid an upfront payment of $0.5 million to the CRO. The upfront payment was capitalized and was recognized as research and development expense using the straight-line method over the term of the agreement, which was one year ending on December 31, 2018. During the year ended December 31, 2018, we recognized a total of $1.1 million of research and development expense under the agreement. During the three and six months ended June 30, 2019, we recognized an insignificant amount of research and development expense under the agreement. During the three and six months ended June 30, 2018, we recognized a total of $0.4 million and $0.7 million, respectively, of 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 June 30, 2019 or 2018. 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 a third party contract research organization to provide antibody discovery related services. Under the agreement, we paid an upfront payment of $0.1 million to the CRO. The upfront payment was capitalized and recognized as research and development expense as the services are delivered. During the three and six months ended June 30, 2019, we recognized a total of $0.4 million of research and development expense under the agreement. We are also 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 June 30, 2019. 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.

Critical Accounting Policies and Use of Estimates

This discussion and analysis of financial condition and results of operation is based on our unaudited condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or 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.

Other than adoption of Topic 842, *Leases*, 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, 2018 with the SEC on March 28, 2019. 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 28, 2019.

Leases

Prior to January 1, 2019, we assessed agreements to determine whether the arrangement was or contained a lease at the inception of the arrangement and if such a lease is classified as a financing or operating lease. For all of our leases accounted for as operating leases, the lease expense was expensed on a straight-line basis over the term of the lease. Our lease agreements contained rent holidays, scheduled rent increases and renewal options. Rent holidays and scheduled rent increases were included in the determination of rent expense and recorded ratably over the lease term. We did not assume renewals in its determination of the lease term unless they were deemed to be reasonably assured at the inception of the lease. We begin recognizing rent expense on the date that we obtain the legal right to use and control the leased space. Deferred rent consisted of the difference between cash payments and the recognition of rent expense on a straight-line basis for the buildings we occupied.

Funding of leasehold improvements by our landlord was accounted for as a tenant improvement allowance and recorded as current and non-current deferred rent liabilities and amortized on a straight- line basis as a reduction of rent expense over the term of the lease.

In certain arrangements, we were involved in the construction of improvements to buildings we are leasing. To the extent we were involved with the structural improvements of the construction project or took construction risk, we were considered to be the owner of the building and related improvements for accounting purposes during the construction period. Therefore, we recorded the fair value of the building subject to the lease within property and equipment on the balance sheet, plus the amount of building improvements incurred and funded by us and/or the landlord as of the balance sheet date. We also recorded a corresponding lease financing obligation on our balance sheet representing the amounts financed by the lessor for the building and lessor financed improvements. Lessor financed improvement incentives due but not yet received were recorded as prepaid expense and other current assets on the balance sheet.

Once construction was completed, we considered the requirements for sale-leaseback accounting treatment, including evaluating whether all risks of ownership had been transferred back to the landlord, as evidenced by a lack of our continuing involvement in the leased property. If we concluded the arrangement did not qualify for sale-leaseback accounting treatment, the building and improvements remained on our balance sheet and were subject to depreciation and assessment of impairment. We bifurcated our lease payments into a portion allocated to the lease financing obligation and a portion allocated to the parcel of land on which the building had been built. The portion of the lease payments allocated to the land was treated for accounting purposes as operating lease payments, and therefore was recorded as rent expense in the statements of operations and comprehensive loss. The portion of the lease payments allocated to the lease financing obligation was further bifurcated into a portion allocated to interest expense and a portion allocated to reduce the lease financing obligation.

The interest rate used for the lease financing obligation represented our estimated incremental borrowing rate at the inception of the lease, adjusted to reduce any built-in loss. The initial recording of these assets and liabilities was classified as non-cash investing and financing items, respectively, for purpose of the statements of cash flows.

The most significant estimates used by management in accounting for the lease financing transaction and the impact of its estimates were as follows:

- *Incremental borrowing rate*. We estimated our incremental borrowing rate as the rate we would have incurred to borrow, based on our credit quality at the inception of the lease over a similar term, the funds necessary to purchase the leased building subject to the financing lease transaction. The incremental borrowing rate was used in determining allocating our rental payments between interest expense and a reduction of the outstanding lease financing obligation.

- *Land capitalization rate*. The land capitalization rate was the rate of return on the land underlying the lease properly considering expected income that the land would be expected to generate. The land lease capitalization rate was estimated using comparable market data for land capitalization rates for similar properties. The land capitalization rate was used in determining allocating our rental payments between interest expense and a reduction of the outstanding lease financing obligation.

- *Fair value of leased building and underlying land*. The fair value of a leased building and underlying land subject to the lease financing transaction was based on comparable market data for similar properties as of the lease inception date. The fair value of the underlying land was used in determining allocating our rental payments between interest expense and a reduction of the outstanding lease financing obligation.

In March 2017, we entered into a non-cancelable lease for 42,620 square feet of office, cleanroom, and laboratory support manufacturing space in Pleasanton, California. Subsequently, in April 2017, we took possession of the space. The scope of the tenant improvements did not qualify under the lease accounting guidance as “normal tenant improvements” and we were the deemed owner of the leased building during the construction period for accounting purposes. In November 2017, construction on the facility was substantially completed and the leased property was placed into service. We determined that the completed construction project did not qualify for sale-leaseback accounting due to the collateral held by the landlord in the form of a letter of credit and will instead be accounted for as a financing transaction. The leased building for the Pleasanton facility and related improvements remains on our balance sheet as of December 31, 2018 and rental payments associated with the lease were allocated to operating lease expense for the ground underlying the leased building and principal and interest payments on the lease financing obligation.

Subsequent to adoption of Topic 842 on January 1, 2019, we determine 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. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. We have elected not to recognize on the balance sheet leases with terms of one year or less. Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, we utilize the appropriate incremental borrowing rate, which is the rate 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 right-of-use asset may be required for items such as initial direct costs paid or incentives received and impairment charges if we determine the right-of-use asset is impaired.

We consider a lease term to be the noncancelable period that it has the right to use the underlying asset, including any periods where it is reasonably assured we 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.

We recognize lease expense on a straight-line basis over the expected lease term.

Our facilities operating leases have lease and non-lease components which we have elected to account for as one single lease component. The lease components resulting in a right-of-use asset have been recorded on the condensed balance sheet and amortized as lease expense on a straight-line basis over the lease term.

Recent Accounting Pronouncements

Refer to "Note 2. Summary Of Significant Accounting Policies" in the notes to our unaudited interim condensed financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q, 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, 2018.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of June 30, 2019, management, with the participation of our Chief Executive Officer and Chief Financial Officer, 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 Chief Executive Officer and the Chief Financial Officer, 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 June 30, 2019, 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 June 30, 2019 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 Quarterly 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. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

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

We are an early-stage biopharmaceutical 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.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are an early-stage biopharmaceutical company, and we have only a limited operating history upon which you can evaluate our business and prospects. We have no products approved for commercial sale, have not generated any revenue from product sales and have incurred losses in each year since our inception in August 2015. In addition, we have limited experience and 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 biopharmaceutical industry. We only recently initiated our Phase 1/2 clinical trials, GO-004 for our first personalized cancer immunotherapy candidate, GRANITE-001, and GO-005 for our off-the-shelf cancer immunotherapy candidate, SLATE-001.

We have had significant operating losses since our inception. Our net losses were $21.2 million and $39.2 million for the three and six months ended June 30, 2019 and $15.5 million and $28.8 million for the three and six months ended June 30, 2018. As of June 30, 2019, we had an accumulated deficit of $165.7 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. GRANITE-001 and SLATE-001, as well as our BiSAb program, will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. In addition, we expect to incur additional costs associated with operating as a public company. We also do not yet have a sales organization or commercial infrastructure and, accordingly, 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 GRANITE-001, SLATE-001, the BiSAb program and any future product candidates, conduct clinical trials and pursue research and development activities. Even if we achieve profitability 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 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 working to establish our in-house manufacturing capabilities. Preclinical studies and clinical trials and additional research and development activities will require substantial funds to complete. As of June 30, 2019, we had capital resources consisting of cash, cash equivalents and marketable securities of $181.7 million. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the development of GRANITE-001, SLATE-001, our BiSAb program, and any other future cancer immunotherapy 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 GRANITE-001 and SLATE-001 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 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-001, SLATE-001 or any future immunotherapy product candidates.

We believe that our existing cash, cash equivalents and marketable securities, including the net proceeds to us from the underwritten public offering of our common stock that we completed in April 2019, will be sufficient to fund our planned operations for at least 12 months and through preliminary safety and efficacy data for both Phase 1/2 clinical trials for GRANITE-001 and SLATE-001. 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 or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. 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 our tumor-specific immunotherapy product candidates, and conducting preclinical studies and clinical trials, including our Phase 1/2 clinical trial for GRANITE-001, which we initiated in the fourth quarter of 2018;
- the scope, progress, results and costs of conducting studies and clinical trials for our SLATE product candidate series, including the Phase 1/2 clinical trial for SLATE-001, which we initiated in mid-2019;
- the scope, progress, results and costs of conducting drug discovery, preclinical studies and clinical trials for our BiSAb program, for which we expect to select a product candidate in the second half of 2019;
- the timing of, and the costs involved in, obtaining regulatory approvals for our tumor-specific immunotherapy 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 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 tumor-specific immunotherapy 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 rights or jointly own some aspects of our technologies or product candidates that we would otherwise pursue on our own. We do not

expect to realize revenue from sales of products or royalties from licensed products in the foreseeable future, if at all, and 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 these 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 limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate 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. These 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 tumor-specific 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 cancer immunotherapy products, if approved, which may vary significantly over time;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The 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 have met any previously publicly stated revenue or earnings guidance we may provide.

Risks Related to Our Business

Our business is dependent on the successful development, regulatory approval and commercialization of our personalized immunotherapy product candidate, GRANITE-001, and our "off-the-shelf" immunotherapy product candidate, SLATE-001, both of which have recently entered clinical trials.

We have no products approved for sale. Both GRANITE-001 and SLATE-001 are in the early stages of clinical trials. As such, we face significant translational risk with GRANITE-001 and SLATE-001 specifically and our tumor-specific immunotherapy approach generally. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of GRANITE-001 and SLATE-001, as well as other product candidates derived from our tumor-specific immunotherapy approach, which may never occur. In the future, we

may also become dependent on other product candidates that we may develop or acquire; however, no product candidates based on our tumor-specific immunotherapy approach have been tested in humans and given our early stage of development, it may be many years, if at all, before we have demonstrated the safety and efficacy of a personalized immunotherapy treatment sufficient to warrant approval for commercialization.

We have not previously submitted a biologics license application, or BLA, to the FDA or similar regulatory approval filings 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, GRANITE-001, SLATE-001 or any future 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 generally is similar in other countries, in order to obtain separate regulatory approval in other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of 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 a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete IND-enabling studies and successfully submit an IND for future product candidates;
- 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;
- 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;
- 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 personalized and “off-the-shelf” immunotherapy 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 current good manufacturing practices, or cGMPs;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy 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 lead product candidate 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 personalized cancer immunotherapy approach;
- our ability to successfully develop a commercial strategy and thereafter commercialize GRANITE-001, SLATE-001 or any future product candidates 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 candidate 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 candidate or any future product candidates to continue our business or achieve profitability.

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.

We are using our proprietary EDGE tumor-antigen prediction platform to develop tumor-specific immunotherapy product candidates to treat cancer. Our foundational science and product development approach are based on our ability to predict the presence of a patient's tumor-specific neoantigens, or 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 T cell activity, 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 that that even if we are able to develop personalized 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. As such, we believe the FDA has limited experience with evaluating our 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 and adverse effect on our business, financial condition, results of operations and prospects.

In addition, 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. For example, regulatory requirements governing cell therapy and gene therapy products have changed frequently and may continue to change in the future. In addition to the submission of an IND to the FDA, before initiation of a clinical trial in the United States, certain human clinical trials subject to the NIH Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines were historically subject to review by the Recombinant DNA Advisory Committee, or RAC. On April 25, 2019, the NIH finalized a proposal to remove protocol submission and reporting requirements and to eliminate the role of the RAC in human gene transfer research. The previous RAC has been renamed the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC), which will advise the NIH Director on the scientific, safety, ethical, and social issues associated with emerging biotechnologies. These trials will remain subject to the FDA's oversight and other clinical trial regulations, and oversight at the local level will continue as otherwise set forth in the NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or 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. Thus, even though we are no longer required to submit a protocol for our product candidates to NIH, we will still be subject to significant regulatory oversight by the FDA and the applicable IBC and IRB of each institution at which we or our collaborators conduct clinical trials of our product candidates, and changes in applicable regulatory guidelines may lengthen the regulatory review process for our product candidates, require additional studies or trials, increase development costs, lead to changes in regulatory positions and interpretations or delay or prevent approval and commercialization of such product candidates.

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.

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. Although we initiated our Phase 1/2 clinical trials, GO-004 in the fourth quarter of 2018 and GO-005 in mid-2019, we may experience delays in enrolling or completing those trials. Additionally, we cannot be certain that studies or trials for GRANITE-001, SLATE-001 or any future 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:

- 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, and, where required, IBC approval at each trial site;
- recruiting an adequate number of suitable patients to participate in a trial;
- 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 candidate for use in preclinical studies or clinical trials from third-party suppliers; or
- accessing checkpoint inhibitors for use in combination with our product candidate in preclinical studies or clinical trials, including checkpoint inhibitors that have not been approved by the FDA for such use.

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;
- 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 personalized 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 non-compliance 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 IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or 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, 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 GRANITE-001, SLATE-001, any future product candidates or our TSNA 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 and adverse effect on our business, financial condition, results of operations and prospects.

As a result of our trial design for GO-004 and GO-005, the Phase 1 portion of the trials will provide little evidence of the efficacy of our personalized immunotherapy product candidate, GRANITE-001 and the off-the-shelf immunotherapy candidate, SLATE-001, 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 and GO-005, will, consequently, involve administration of a combination therapy with GRANITE-001 and SLATE-001, respectively. Notably, all patients in the Phase 1 portion of these trials will receive anti-PD-1 monoclonal antibodies, or mAb, as background therapy. Some patients in both trials will additionally receive 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 Phase 1 trials will thus be in patients receiving our experimental therapy together with a checkpoint inhibitor and attribution of objective responses to the effects of GRANITE-001 or SLATE-001 alone will not be possible. We expect that efficacy will be studied carefully in the respective programs' Phase 2 cohorts, in which the relative contributions of our personalized and off-the-shelf immunotherapy candidates and the checkpoint inhibitors will be dissected and quantified to some degree. 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 that means our selected patients would have a clinical outcome upon standard therapy which is superior to unselected case controls. As a result, interpretation of "time-to-event" endpoints such as progression-free survival or overall survival will be challenging without a contemporaneous, randomized control group. As a result, the Phase 1 portions of our respective Phase 1/2 clinical trials will provide little evidence of the efficacy of GRANITE-001 or SLATE-001, which may not be fully understood by investors or market participants, potentially leading to negative effects on our stock price.

We may be unable to obtain regulatory approval for our tumor-specific immunotherapy 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.

To gain approval to market our tumor-specific immunotherapy product candidates, we must provide the FDA and foreign regulatory authorities with clinical data that adequately demonstrate the safety 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, 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.

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 and effective for the requested indication;
- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocol or the interpretation 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-001, SLATE-001 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.

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. The FDA or the applicable foreign regulatory agency also may approve our lead product candidate 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 personalized immunotherapy candidate, GRANITE-001, and our off-the-shelf immunotherapy candidate, SLATE-001. 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 may be more profitable.

We are currently developing our personalized cancer immunotherapy candidate based on the prediction of a patient's TSNA, in order to address a variety of cancers, including metastatic non-small cell lung cancer, or NSCLC, and gastroesophageal, bladder and colorectal cancers. Our off-the-shelf product candidate clinical trial will address mutation positive and metastatic and advanced solid tumors, including NSCLC, colorectal and pancreatic cancers. We have strategically determined to initially focus solely on the development of personalized 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.

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.

In order for our tumor-specific immunotherapy candidates, GRANITE-001 and SLATE-001, to be commercially optimized, they would ideally be utilized in early lines of cancer treatment as well as later lines of treatment.

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 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 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. Tumor-specific immunotherapy product candidates such as GRANITE-001, as well as "off-the-shelf" product

candidates such as SLATE-001, are expected to be administered in combination with checkpoint inhibitors and can, in principle, be safely used in early lines of therapy. Our 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 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 product candidates both as late-line therapy where appropriate, but also as a second line and 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 second-line or first-line or adjuvant therapy.

While our SLATE product is designed to be readily available (off-the-shelf), our GRANITE-001 will initially take approximately 16-20 weeks to be manufactured and released for human use, and this 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 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.

We may not be successful in our efforts to create a pipeline of immunotherapy candidates or to develop commercially successful products. If we fail to successfully develop additional product candidates, our commercial opportunity may be limited.

We are committed to developing personalized cancer immunotherapies to fight multiple cancer types and are currently advancing multiple product candidates to address a variety of cancers, including metastatic NSCLC and colorectal, gastroesophageal, pancreatic, bladder cancers as well as other mutation-positive cancers in our SLATE-001 program. Utilizing our EDGE platform, we believe we can develop multiple therapeutic classes of products that will generate a T cell immune response unleashing the natural power of the immune system on the tumor cells. However, one or more of these alternative therapeutic products may never be successfully validated in a human. In addition, identifying, developing, obtaining regulatory approval for and commercializing therapies for the treatment of cancer will require substantial additional funding and is prone to the risks of failure inherent in therapeutic product development. Research programs to identify product candidates also require substantial technical, financial and human resources, regardless of whether or not any product candidates are ultimately identified, and even if our research programs initially show promise in identifying potential product candidates, they may fail to yield product candidates for clinical development.

We therefore cannot provide any assurance that we will be able to successfully identify additional product candidates, advance any of these additional product candidates through the development process, successfully commercialize any such additional product candidates, if approved, or assemble sufficient resources to identify, acquire, develop or, if approved, commercialize additional product candidates. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunity may be limited.

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;
- 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. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

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 tumor-specific immunotherapy 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 only just initiated patient dosing in our clinical trials of GRANITE-001 and SLATE-001 and do not have a comprehensive understanding of its risks, it is likely that there will be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted, 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 tumor-specific immunotherapy 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.

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 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, or REMS, 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 and 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 and adverse effect on our business, financial condition, results of operations and prospects.

Even if one of our tumor-specific immunotherapy 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 tumor-specific immunotherapy 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. For a variety of reasons, including among other things, competitive factors, pricing or physician preference, reimbursement by insurers, 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 personalized 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-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 requirement for a REMS;
- 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 manufacture a portion of our initial product candidate internally and rely on qualified third parties to supply components of our initial product candidate. Our inability to manufacture sufficient quantities of GRANITE-001, SLATE-001 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 and adversely affect our business.

Manufacturing is a vital component of our tumor-specific immunotherapy approach and we have invested significantly in our manufacturing facility. To ensure timely and consistent product supply assurance to our patients we currently use a hybrid product supply approach whereby certain elements of our initial product candidate are manufactured internally at our manufacturing facilities in Pleasanton, California, and other elements are manufactured at qualified third-party contract manufacturing organizations, or CMOs. All internal and third party contract manufacturing is performed under cGMP guidelines. We plan to internalize a majority of the manufacturing steps in the supply chain to optimize cost and production time, as well as establish full control over intellectual property and product quality. To do so, we will need to continue to scale up our manufacturing operations, as we do not currently have the infrastructure or capability internally to manufacture all supplies needed for our product candidates or the materials necessary to produce our product candidates for use in the conduct of our preclinical studies or clinical trials, and 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.

In addition, 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, we and our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If we or our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized.

Our tumor-specific 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 tumor-specific immunotherapy product candidates, GRANITE-001 and SLATE-001, are considered to be biologics and the manufacturing processes are complex, time-consuming, highly-regulated and subject to multiple risks. The manufacture of our product candidate GRANITE-001 involves extraction of genetic material from patient tumor samples, while SLATE-001 is designed using known genetic sequences available from public databases. Both GRANITE-001 and SLATE-001 require genetic manipulations at the gene sequence level, live cell culture operations, specialized formulations and aseptic fill finish operations. As a result of these complexities, the cost to manufacture biologics in general, and our personalized immunotherapy GRANITE-001, in particular, is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and more difficult and time-consuming to reproduce. For example, the entire cGMP manufacturing process from biopsy receipt to the release and shipment of GRANITE-001 to the clinical site for patient administration will initially take approximately 16-20 weeks. In addition, our manufacturing process for both GRANITE-001 and SLATE-001 are in their early 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-001 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-001 and SLATE-001, we also may make changes to our manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials 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 course of clinical development 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 an extended period 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 manufacture of our product candidates will not occur in the future.

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 personalized 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 competitors that are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any 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 meet expected deadlines, we may be unable to obtain regulatory approval for our tumor-specific immunotherapy product candidates.

We currently do not have the ability to independently conduct preclinical studies that comply with the regulatory requirements known as good laboratory practice, or GLP, 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, or 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 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 would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for thirty five days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We face significant competition in an environment of rapid technological and scientific change, and we will face significant competition 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.

If either of GRANITE-001 or SLATE-001 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.

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. 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 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 European Union 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.

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 personalized 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 extend our EDGE platform based on additional tumor data collected from our clinical trials 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 our own sales force and distribution systems. 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 product candidates 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 June 30, 2019, we had 143 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our lead product candidate 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 and 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 lead product candidate 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. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies 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 collaboration with bluebird bio, or any future collaboration arrangements that we may enter into, may not be successful, which could significantly limit the likelihood of receiving the potential economic benefits of the collaboration and adversely affect our ability to develop and commercialize our product candidates.

In August 2018, we entered into a strategic collaboration with bluebird bio to utilize our EDGE platform to identify and validate tumor-specific targets and provide TCRs directed to ten selected targets for use in bluebird bio's cell therapy products. Under the collaboration, 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 bluebird bio's cell therapy products utilizing the TCRs we develop directed at the targets we discovered. In addition, 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, any collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain and challenging to manage. We may not be successful in our efforts with bluebird bio and we may never receive any milestone or royalty payments. Further, we may be unable to prudently manage our existing collaboration or to enter new ones should we chose to do so. The terms of 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 not 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 earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

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. 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 damage from computer viruses, malware, 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. 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, if applicable, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009, or HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

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 be in compliance 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 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 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 and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, 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.

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 issues 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 June 30, 2019, our solely owned patent portfolio includes 19 pending U.S. patent applications and 56 pending foreign patent applications and one issued U.S. patent relating to the use of a predictive model to identify neoantigens, particularly where the predictive model was trained using mass spectrometry data. 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, or USPTO, 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 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 biopharmaceutical 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 on a substantial scale, if approved, 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 agreement with Arbutus Biopharma Corporation for certain lipid nanoparticle-based delivery technologies. This 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 U.S. Serial Nos. 15/187,174 and 14/794,449, expiring in May 2031 (absent any patent term adjustments or extensions), directed to certain methods of identifying and using neoantigens. If a patent issues from such patent applications with claims similar to those that are currently pending, our ability to commercialize GRANITE-001 in the United States may be adversely affected if we do not obtain a license under such patent. In addition, 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 the company's 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, or 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, or 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 our reply is due in August 2019. If, after appeal, EP Patent 2569633 is ultimately maintained by the EPO with claims similar to those that are currently opposed, our ability to commercialize GRANITE-001 in certain European countries may be adversely affected if we do not obtain a license under the patent.

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 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 GRANITE-001, SLATE-001 or our other 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 GRANITE-001, SLATE-001 or our other 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 GRANITE-001, SLATE-001 or any future 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 GRANITE-001, SLATE-001 or any future 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 GRANITE-001, SLATE-001 or any future 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 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-001 and SLATE-001, in particular, our agreement with Arbutus. 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 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, these 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 under these agreements.

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

As is common in the 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 in defending 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 in defending 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-001, SLATE-001 or any future immunotherapy 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 tradenames 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 recent 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, or 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 US 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 personalized cancer 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 regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any 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, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We 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 EMA's Committee for Orphan Medicinal Products, or 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 or where 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.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and application fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication 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 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. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

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 with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or EMA 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.

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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively 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;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting “transfers of value” made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- 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.

Since its enactment, there have been judicial, Congressional, and executive branch challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, was enacted, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Since the enactment of the Tax Act, there have been additional amendments to certain provisions of the ACA. Most recently, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Trump Administration and CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the ACA will impact the ACA and 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 2027 unless additional action is taken by Congress. 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.

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 and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. The Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

In the European Union, 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.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

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 rebate), 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. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. 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;
- HIPAA, as amended by HITECH, and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information on their behalf;
- the FDCA, 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 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; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- 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;
- 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 to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, 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-001, SLATE-001 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/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 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 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; 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 the 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.

An active, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock.

Prior to our initial public offering in September 2018, there was no public market for shares of our common stock. Our stock only recently began trading on the Nasdaq Global Select Market, but we can provide no assurance that we will be able to maintain an active trading market on the Nasdaq Global Select Market or any other exchange in the future. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications, or technologies using our shares as consideration.

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 significant costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives. 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 Securities and Exchange Commission, or 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. Our management and other personnel devote a substantial amount of time to ensure that we comply with all of these 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, or 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. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of 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 date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. 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. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend on CROs 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.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

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

As of June 30, 2019, our executive officers, directors and their respective affiliates held over a majority of our outstanding voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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 after the lock-up and other legal restrictions on resale related to our most recent public offering lapse, the trading price of our common stock could decline. As of June 30, 2019, we have outstanding a total of 35,769,043 shares of common stock.

The lock-up agreements entered into in connection with our public offering in April 2019 have expired, and up to approximately 10.9 million additional shares of common stock held by directors, executive officers and other affiliates are eligible for sale in the public market, subject to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

In addition, as of June 30, 2019, approximately 6.1 million shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity incentive plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. 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.

Further, as of June 30, 2019, the holders of approximately 8.8 million shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting schedules and to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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 and do not expect to become profitable in the near future, and we 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, or the 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, or NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. In connection with our initial public offering which closed in October 2018, we performed an IRC Section 382 and 383 analysis and determined we had an ownership change. There was no reduction in federal or California net operating loss carryforwards or research and development income tax credits as a result of this ownership change. Any equity financing transactions, private placements, and other transactions that may occur within the specified three-year 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. Furthermore, under recently enacted U.S. tax legislation, although the treatment of tax losses generated before December 31, 2017 has generally not changed, tax losses generated in calendar year 2018 and beyond may only offset 80% of our taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

Recent U.S. tax legislation and future changes to applicable U.S. tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.

Changes in laws and policy relating to taxes may have an adverse effect on our business, financial condition and results of operations. For example, the U.S. government recently enacted significant tax reform legislation, and certain provisions of the new law may adversely affect us. Changes include, but are not limited to, a federal corporate income tax rate decrease to 21% for tax years beginning after December 31, 2017, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017, eliminating carrybacks of net operating losses, and providing for indefinite carryforwards for losses generated in tax years after December 31, 2017. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial condition and results of operations.

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.

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.

Our amended and restated certificate of incorporation 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 provides that 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, any action to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. Similarly, 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. 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. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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

There were no unregistered sales of equity securities by us during the quarter ended June 30, 2019.

Use of Proceeds

On September 27, 2018, the U.S. Securities and Exchange Commission declared effective our registration statement on Form S-1 (File Nos. 333-226976), as amended, filed in connection with our IPO. The IPO closed on October 2, 2018 and we issued and sold 6,666,667 shares of our common stock at a price to the public of $15.00 per share. On October 31, 2018, the underwriters exercised their option to purchase additional shares with respect to 187,535 shares of our common stock, at a price to the public of $15.00 per share. We received gross proceeds from the IPO, including from the exercise of the underwriters' option to purchase additional shares, of approximately $102.8 million, before deducting underwriting discounts and commissions of approximately $7.2 million. The managing underwriters of the offering were Goldman Sachs & Co. LLC, Cowen and Company, LLC, Barclays Capital Inc. and BTIG, LLC. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

The net proceeds from the IPO have been invested in short-term, interest-bearing, investment-grade securities and government securities. There has been no material change in the expected use of the net proceeds from our IPO as described in our registration statement on Form S-1.

Issuer Purchases of Equity Securities

The table below summarizes our stock repurchase activity for the quarter ended June 30, 2019.

Fiscal Period	Total Number of Shares Repurchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of a Publicly Announced Program	Maximum Number (or Approximate Dollar Value) of Shares that May Yet be Purchased Under the Program
April 1 to April 30, 2019	—	$ —	—	N/A
May 1 to May 31, 2019	8,299	$ 0.35	—	N/A
June 1 to June 30, 2019	—	$ —	—	N/A
Total during quarter ended June 30, 2019	8,299	$ 0.35	—	

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	Amended and Restated Certificate of Incorporation, as amended.	8-K	10/02/2018	3.1	
3.2	Amended and Restated Bylaws.	8-K	10/02/2018	3.2	
4.1	Reference is made to exhibits 3.1 through3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	09/17/18	4.2	
31.1	Certification of Chief Executive Officer of Gritstone Oncology, 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 Oncology, 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	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				X

* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Gritstone Oncology, 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 Quarterly Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Gritstone Oncology, Inc.

Date: August 12, 2019

By: /s/ Andrew Allen

Andrew Allen
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 12, 2019

By: /s/ Jean-Marc Bellemin

Jean-Marc Bellemin
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 Oncology, Inc.;

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

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

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

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

   (b) 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

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

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

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

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

Date: August 12, 2019

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, Jean-Marc Bellemin, certify that:

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

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

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

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

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

   (b) 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

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

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

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

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

Date: August 12, 2019

By: /s/ Jean-Marc Bellemin
Jean-Marc Bellemin
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 Oncology, Inc. (the "Company") for the period ended June 30, 2019, 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 of the Company, and Jean-Marc Bellemin, Chief 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: August 12, 2019

/s/ Andrew Allen

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

Date: August 12, 2019

/s/ Jean-Marc Bellemin

Jean-Marc Bellemin
Chief Financial Officer
(Principal Financial Officer)